Office of Research Integrity

IRBNet User Manual

6/18/2015

User Manual

The Office of Research Integrity is pleased to provide Ball State researchers with this manual to assist them in using our online protocol submission system, IRBNet. Within this document you will find step by step instructions and assistance with first-time registration, submission, continuing review, modifications, adverse event reporting, and study closure. If you encounter any problems, or have questions regarding the protocol submission process, please contact the Office of Research Integrity.

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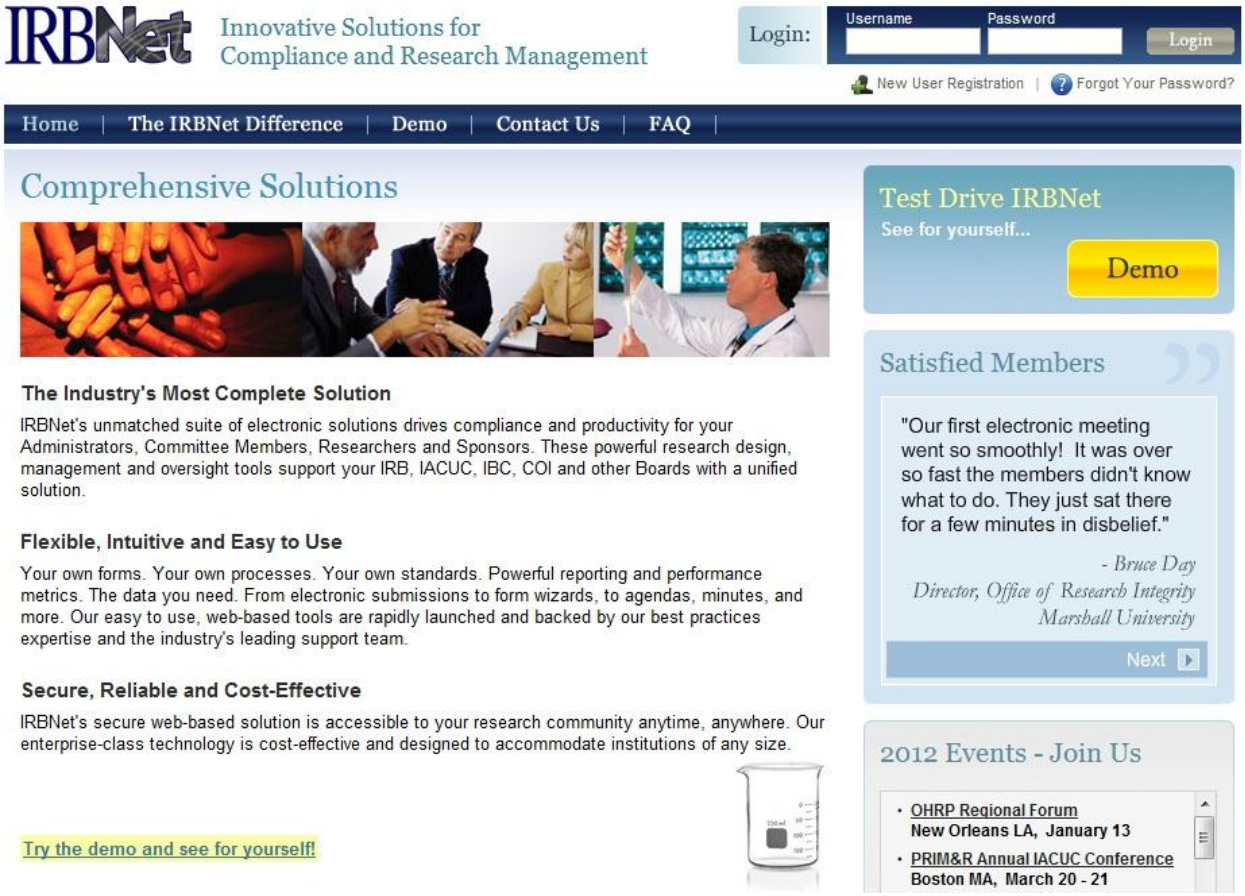
Contents

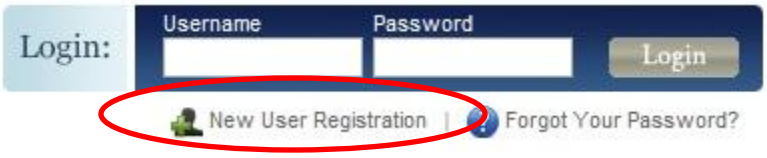
Registration 3
Creating your study 5
Minor Revisions (Unlock) 14
Modification Submission (Deferred letter) 16
Modifying an Approved Study 22
Annual Continuing Review Submission (Expedited and Full Board) 28
Adverse Events Submission 34
Final Report Submission (Expedited and Full Board) 41

Registration

1. Navigate to http://www.irbnet.org


IRBNet
Innovative Solutions for Compliance and Research Management
Login:
Username
Password
Login
New User Registration | Forgot Your Password?
Home | The IRBNet Difference | Demo | Contact Us | FAQ
Comprehensive Solutions
The Industry's Most Complete Solution
IRBNet's unmatched suite of electronic solutions drives compliance and productivity for your Administrators, Committee Members, Researchers and Sponsors. These powerful research design, management and oversight tools support your IRB, IACUC, IBC, COI and other Boards with a unified solution.
Flexible, Intuitive and Easy to Use
Your own forms. Your own processes. Your own standards. Powerful reporting and performance metrics. The data you need. From electronic submissions to form wizards, to agendas, minutes, and more. Our easy to use, web-based tools are rapidly launched and backed by our best practices expertise and the industry's leading support team.
Secure, Reliable and Cost-Effective
IRBNet's secure web-based solution is accessible to your research community anytime, anywhere. Our enterprise-class technology is cost-effective and designed to accommodate institutions of any size.
Try the demo and see for yourself!
Test Drive IRBNet
See for yourself...
Demo
Satisfied Members
"Our first electronic meeting went so smoothly! It was over so fast the members didn't know what to do. They just sat there for a few minutes in disbelief."
- Bruce Day
Director, Office of Research Integrity
Marshall University
Next
2012 Events - Join Us
OHRP Regional Forum
New Orleans LA, January 13
PRIM&R Annual IACUC Conference
Boston MA, March 20 - 21

2. Look for the login box, located in the upper right portion of the website.
3. Click on **"New User Registration"** (as circled).

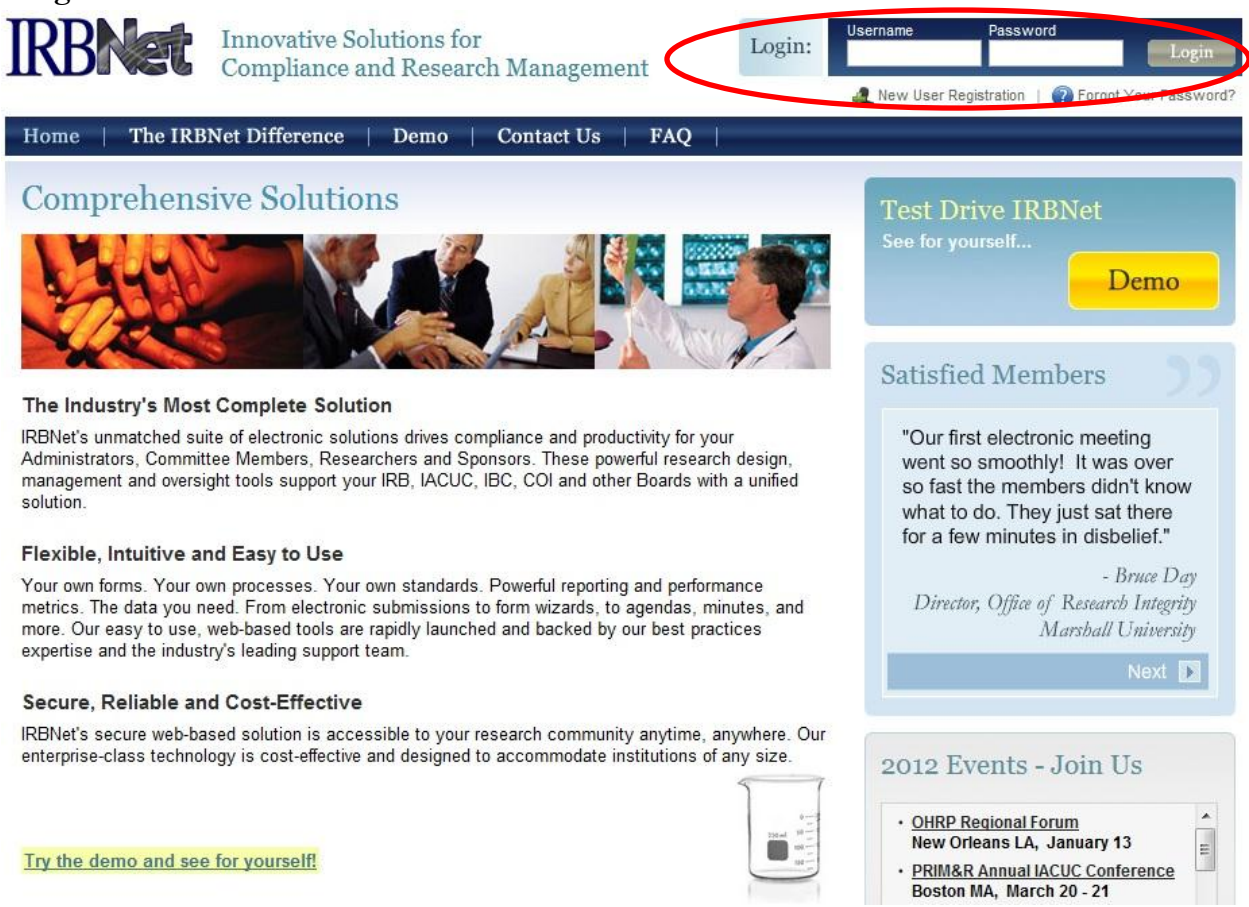


4. Fill in the information necessary to create your account.
5. After you click **"continue"** accept the Terms of Use.

6. Select Ball State University. To do this, type **"Ball State University"** in the **"search for an organization"** space.
7. Click continue and enter your contact information. The e-mail address entered will be the one used to contact you regarding IRB decisions related your future protocol(s).
8. Confirm all the information that you have entered, and be sure that you are listed as a **"Researcher"** at Ball State University.
9. After completing your registration, you will receive an e-mail from IRBNet. Use the provided link within this e-mail to finalize your registration.

Creating your study

1. Navigate to www.irbnet.org and login using the username and password you created from the previous section. If you have not created an account, please follow the necessary steps in the **"Registration"** section of this manual.


IRBNet
Innovative Solutions for
Compliance and Research Management
Login:
Username
Password
Login
New User Registration
Forgot Your Password?
Home | The IRBNet Difference | Demo | Contact Us | FAQ |
Comprehensive Solutions
The Industry's Most Complete Solution
IRBNet's unmatched suite of electronic solutions drives compliance and productivity for your Administrators, Committee Members, Researchers and Sponsors. These powerful research design, management and oversight tools support your IRB, IACUC, IBC, COI and other Boards with a unified solution.
Flexible, Intuitive and Easy to Use
Your own forms. Your own processes. Your own standards. Powerful reporting and performance metrics. The data you need. From electronic submissions to form wizards, to agendas, minutes, and more. Our easy to use, web-based tools are rapidly launched and backed by our best practices expertise and the industry's leading support team.
Secure, Reliable and Cost-Effective
IRBNet's secure web-based solution is accessible to your research community anytime, anywhere. Our enterprise-class technology is cost-effective and designed to accommodate institutions of any size.
Try the demo and see for yourself!
Test Drive IRBNet
See for yourself...
Demo
Satisfied Members
"Our first electronic meeting went so smoothly! It was over so fast the members didn't know what to do. They just sat there for a few minutes in disbelief."
- Bruce Day
Director, Office of Research Integrity
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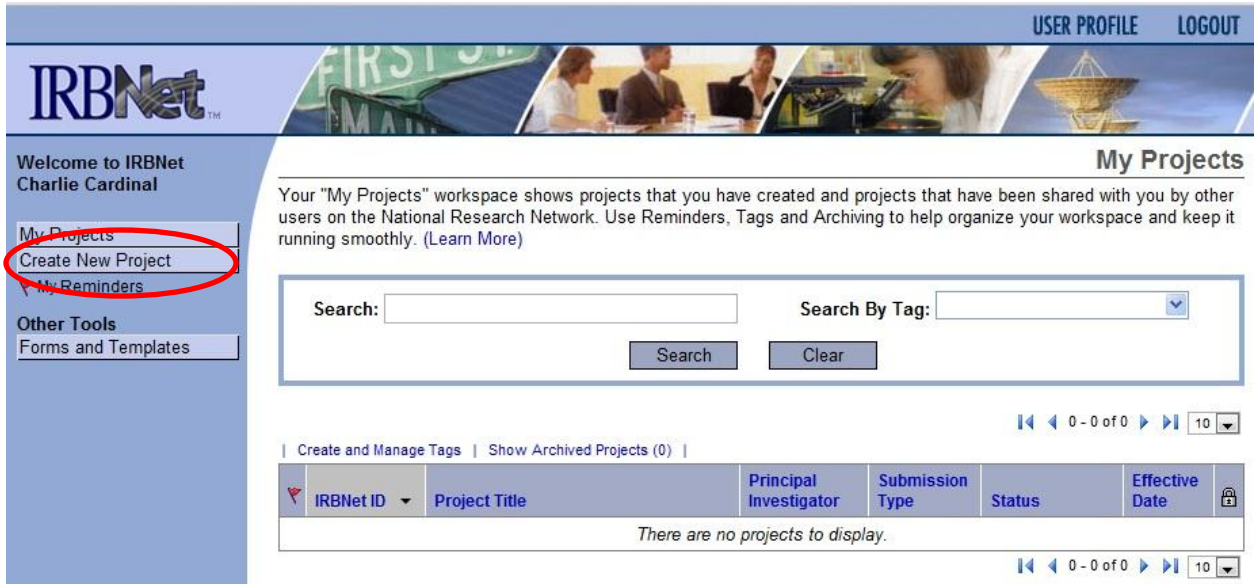
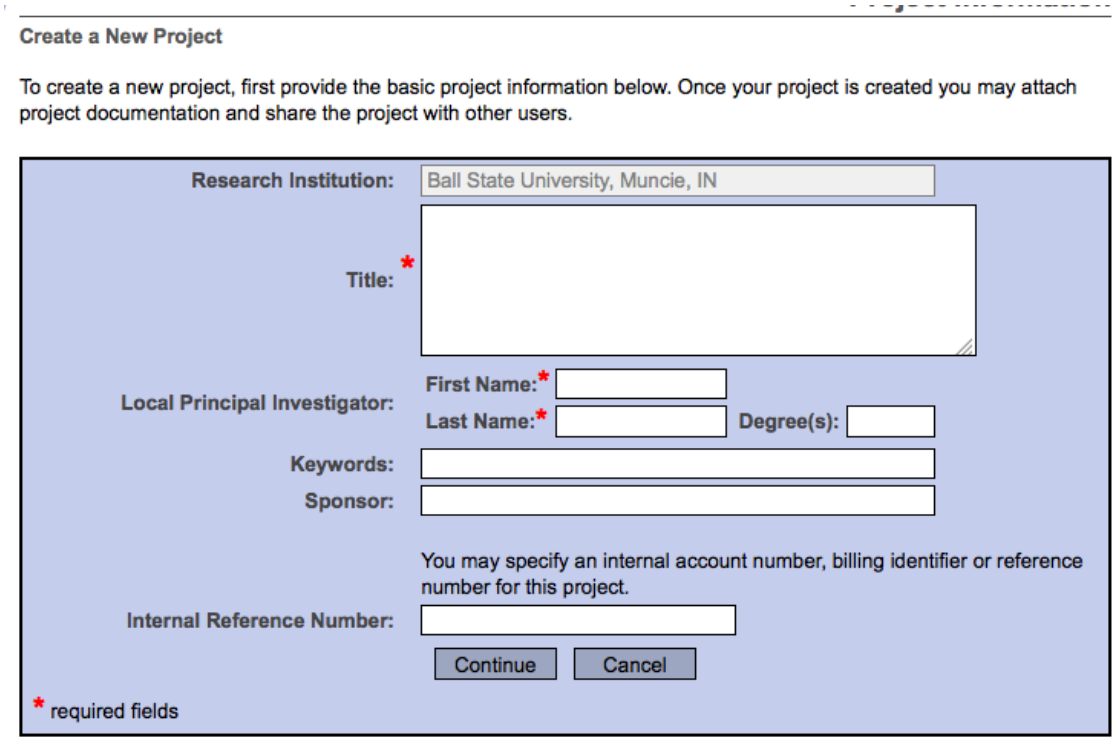
OHRP Regional Forum
New Orleans LA, January 13
PRIM&R Annual IACUC Conference
Boston MA, March 20 - 21

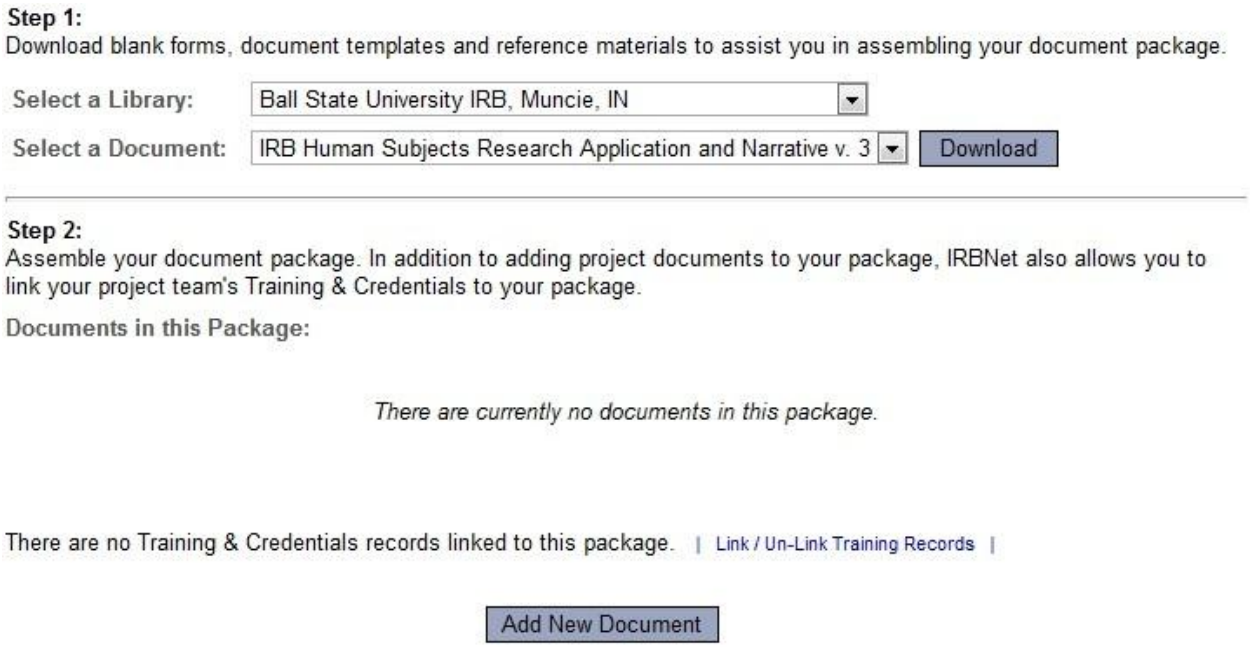
2. On the left side of the page, select **"Create New Project".**


USER PROFILE
LOGOUT
IRBNet
Welcome to IRBNet
Charlie Cardinal
My Projects
Create New Project
My Reminders
Other Tools
Forms and Templates
My Projects
Your "My Projects" workspace shows projects that you have created and projects that have been shared with you by other users on the National Research Network. Use Reminders, Tags and Archiving to help organize your workspace and keep it running smoothly. (Learn More)
Search:
Search By Tag:
Search
Clear
0 - 0 of 0
10
Create and Manage Tags | Show Archived Projects (0) |
IRBNet ID
Project Title
Principal Investigator
Submission Type
Status
Effective Date
There are no projects to display.
0 - 0 of 0
10

3. The following screen will appear:


Create a New Project
To create a new project, first provide the basic project information below. Once your project is created you may attach project documentation and share the project with other users.
Research Institution:
Ball State University, Muncie, IN
Title: *
Local Principal Investigator:
First Name:*
Last Name:*
Degree(s):
Keywords:
Sponsor:
You may specify an internal account number, billing identifier or reference number for this project.
Internal Reference Number:
Continue
Cancel
* required fields

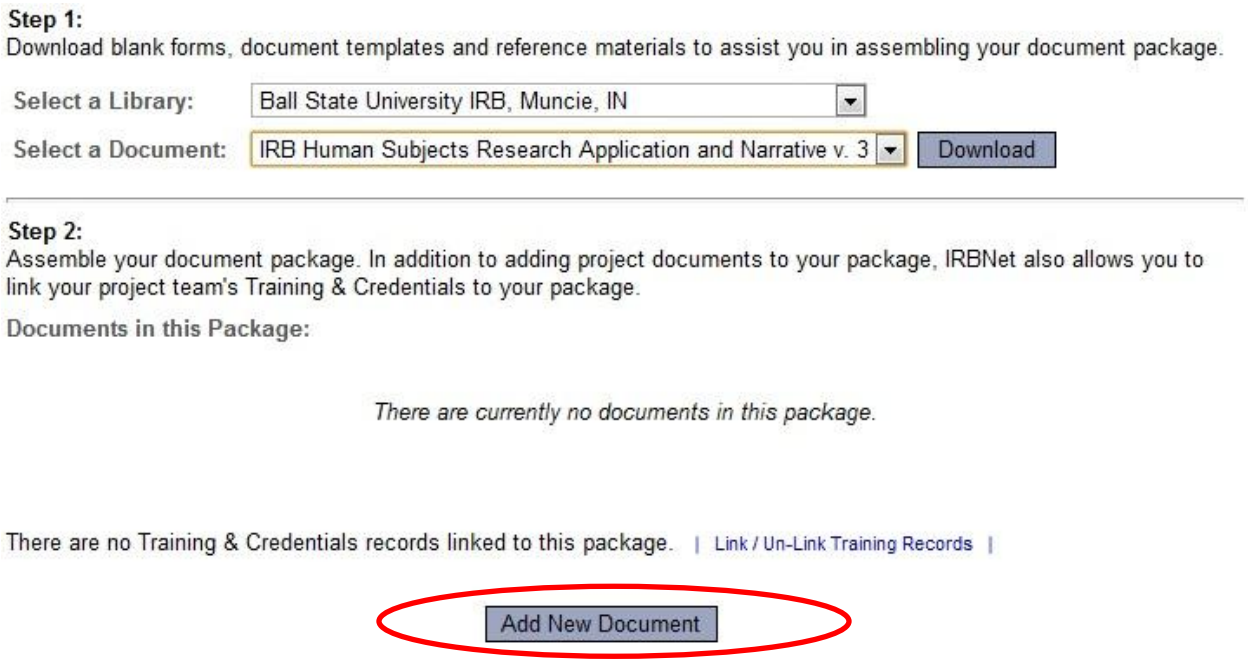
4. Enter the title of the project and your name. If the study is sponsored, please enter the funding agency's name in the sponsor box. The keywords box may be useful for you if you have several studies and need to find this study at a later time based upon a specific keyword.
5. Click **"continue".**
6. You will be taken to the **"Designer"** page, and the following screen will appear:


Step 1:
Download blank forms, document templates and reference materials to assist you in assembling your document package.
Select a Library:
Ball State University IRB, Muncie, IN
Select a Document:
IRB Human Subjects Research Application and Narrative v. 3
Download
Step 2:
Assemble your document package. In addition to adding project documents to your package, IRBNet also allows you to link your project team's Training & Credentials to your package.
Documents in this Package:
There are currently no documents in this package.
There are no Training & Credentials records linked to this package. | Link / Un-Link Training Records |
Add New Document

All forms are located in the Library manager on IRBNet:

7. Make sure you have completed all pieces of the Human Subjects Research Application and Protocol Form and created separate documents for possible recruitment materials, surveys, and informed consent forms.

8. Within the **"Designer"** page, click **"Add New Document"**


Step 1:
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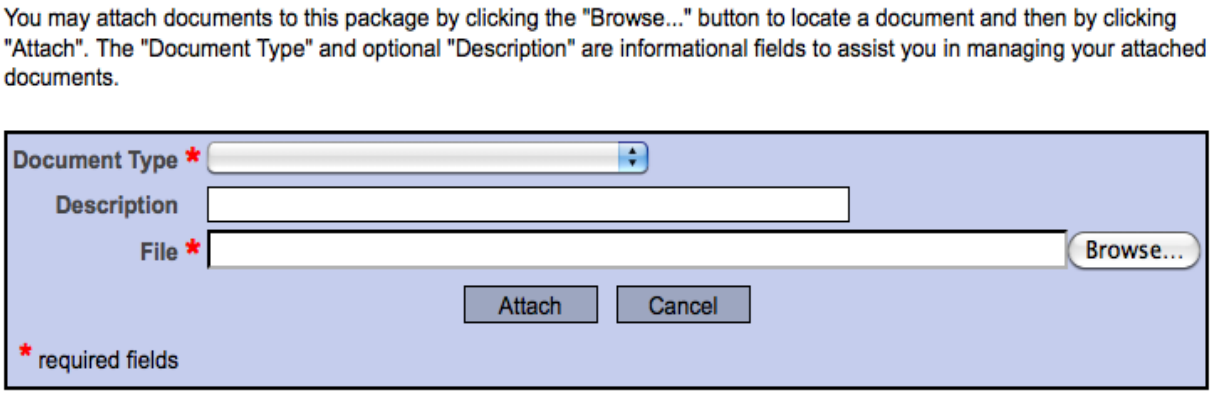
Select a Library:
Ball State University IRB, Muncie, IN
Select a Document:
IRB Human Subjects Research Application and Narrative v. 3
Download
Step 2:
Assemble your document package. In addition to adding project documents to your package, IRBNet also allows you to link your project team's Training & Credentials to your package.
Documents in this Package:
There are currently no documents in this package.
There are no Training & Credentials records linked to this package. | Link / Un-Link Training Records |
Add New Document

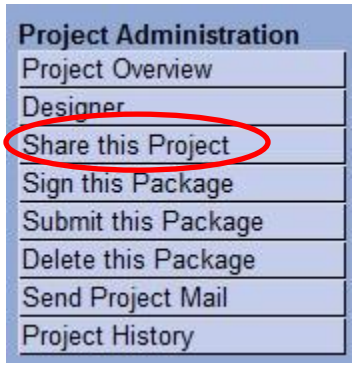
9. Once you click, **"Add New Document"**, this screen will appear:


You may attach documents to this package by clicking the "Browse..." button to locate a document and then by clicking "Attach". The "Document Type" and optional "Description" are informational fields to assist you in managing your attached documents.
Document Type *
Description
File *
Browse...
Attach
Cancel
* required fields

10. Within this Document Type, select **"Application Form"**.
11. Browse for the file on your computer and click **"Attach"**.
12. If you have additional materials (such as a file containing recruitment materials, survey questions, consent forms, proof of CITI training, letter of support, etc), complete these steps again. For document type, select the name that best represents what is in the additional document, or choose **"Other"** and type what the document is in the **"Description"** box.

13. Once all files have been uploaded, you need to share your study with others. **Student PI's must share the project with faculty advisor before submitting.** This could also include other advisors or colleagues. To share your project with another person, the person must be registered with IRBNet.

14. Select the "**Share this Project**" link, located on the left side of the page. This is located under the "Project Administration" heading.

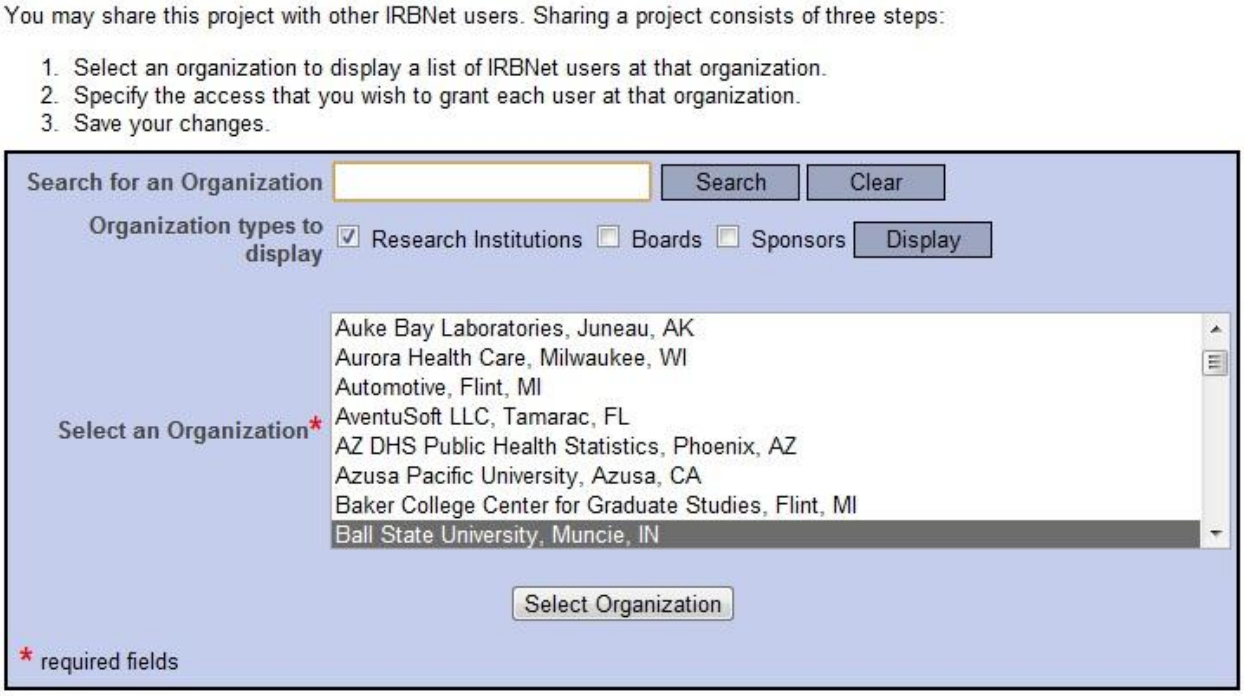


15. The following screen will appear, and you select the first option, **"Share"**:

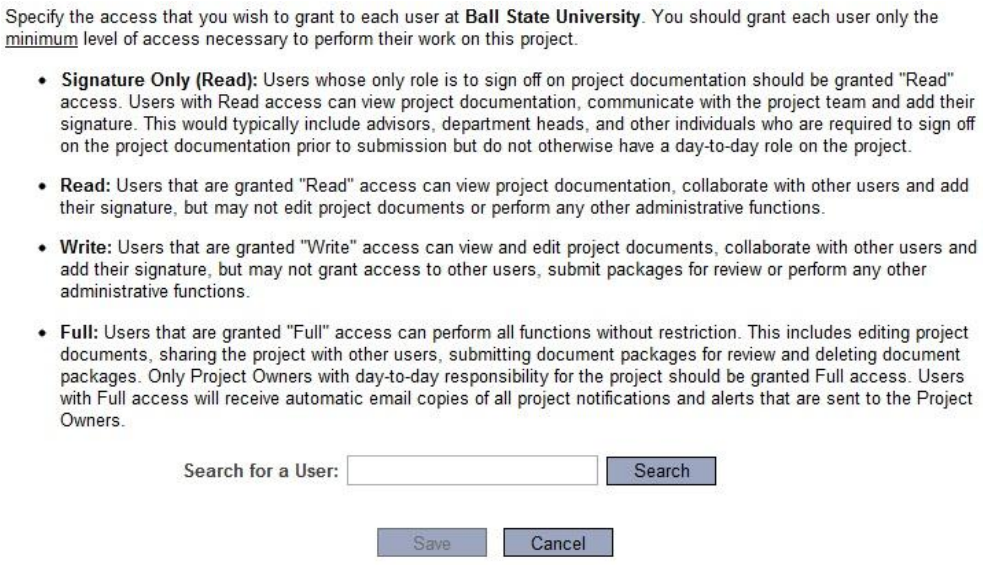
You may share this project with other Researchers, Committee Members, Administrators and Sponsors. You may also send a complete copy of this project to a Principal Investigator at another site if this is a multi-site project. You may also transfer ownership of this project to another individual.

- **Share:** Use this option if you wish to share your project with other Researchers, Committee Members, Administrators or Sponsors at your own institution or any other institution. For example, you may wish to share this project with other members of your research team so that you may collaborate in the design and development of the project, or with a selected Committee Member or Administrator to solicit feedback prior to submitting your project for review. You may provide any individual with **Full**, **Write** or **Read** access.
- **Multi-site:** Use this option only if your project is a multi-site project and you wish to send a complete and independent copy of this project to a Principal Investigator at another site. The local Principal Investigator will be able to obtain project documents from the lead site and may modify their copy of these documents (such as consent forms) to meet the requirements of their local Board. You will be able to monitor the progress of this project at every local site. The other local Principal Investigators will also be able to monitor the progress of this project at every local site (including your own).
- **Transfer:** Transfer your ownership of this project to another user. In doing so you will relinquish all access to this project and the designated user will be granted **Full** access.

16. The following screen will appear, and you can search for the organization with which the person you would like to share the project with is affiliated:

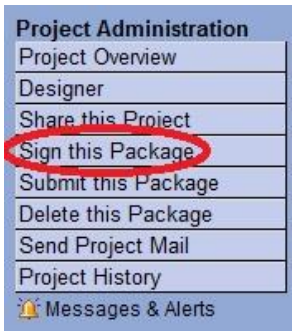

You may share this project with other IRBNet users. Sharing a project consists of three steps:
1. Select an organization to display a list of IRBNet users at that organization.
2. Specify the access that you wish to grant each user at that organization.
3. Save your changes.
Search for an Organization
Search
Clear
Organization types to display
Research Institutions
Boards
Sponsors
Display
Select an Organization*
Auke Bay Laboratories, Juneau, AK
Aurora Health Care, Milwaukee, WI
Automotive, Flint, MI
AventuSoft LLC, Tamarac, FL
AZ DHS Public Health Statistics, Phoenix, AZ
Azusa Pacific University, Azusa, CA
Baker College Center for Graduate Studies, Flint, MI
Ball State University, Muncie, IN
Select Organization
* required fields

17. Once the organization is selected, you will need to search for the specific user using the page below. Please pay attention to the different sharing levels. You may want an advisor or a colleague to have a particular level of access.


Specify the access that you wish to grant to each user at Ball State University. You should grant each user only the minimum level of access necessary to perform their work on this project.
Signature Only (Read): Users whose only role is to sign off on project documentation should be granted "Read" access. Users with Read access can view project documentation, communicate with the project team and add their signature. This would typically include advisors, department heads, and other individuals who are required to sign off on the project documentation prior to submission but do not otherwise have a day-to-day role on the project.
Read: Users that are granted "Read" access can view project documentation, collaborate with other users and add their signature, but may not edit project documents or perform any other administrative functions.
Write: Users that are granted "Write" access can view and edit project documents, collaborate with other users and add their signature, but may not grant access to other users, submit packages for review or perform any other administrative functions.
Full: Users that are granted "Full" access can perform all functions without restriction. This includes editing project documents, sharing the project with other users, submitting document packages for review and deleting document packages. Only Project Owners with day-to-day responsibility for the project should be granted Full access. Users with Full access will receive automatic email copies of all project notifications and alerts that are sent to the Project Owners.
Search for a User:
Search
Save
Cancel

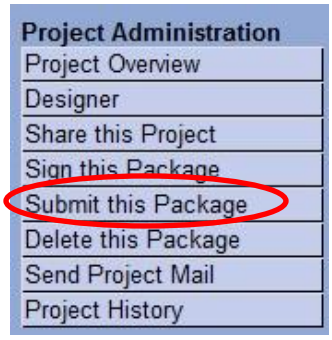
18. Once the user is found, you may grant the appropriate level of access. Within the "Comments" box, you can enter any additional comments that will be included in the e-mail to the specified IRBNet user which notifies them of their new access to your protocol.

19. The next step is to navigate to the "Sign this Package" section. Remember, **student PI's must have faculty advisor sign the package before you can submit the package for review**.

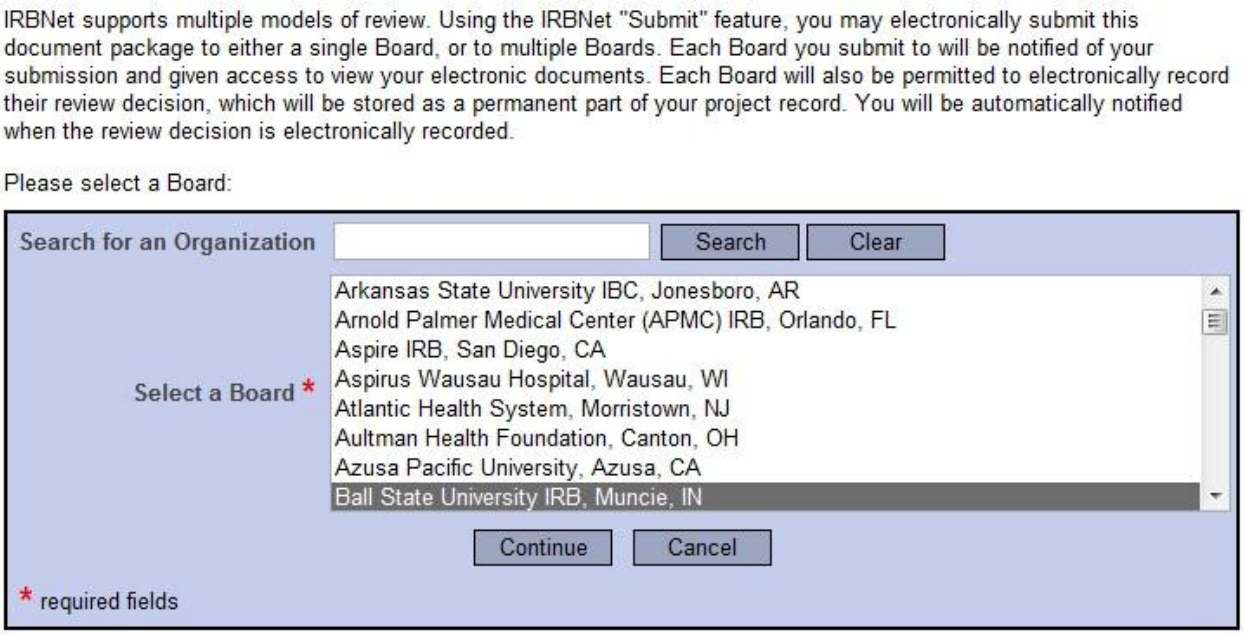


20. Within the "**Sign Package**" page, you will need to select your role in the project. If you are the principal investigator, select this option from the drop down box.

21. Once you click "**Sign**," you will receive a notification from IRBNet that you have signed the package. Anyone else that you selected to share the project with will receive an email notifying them of your signature too. Similarly, when your advisor signs the package, you will receive an email notification.
22. Once everyone has signed the package, you need to submit the package. A package cannot be submitted until everyone has signed the package**. If you have an advisor, the advisor must sign the package before you submit the package to the IRB for review**.
23. Unless all signatures are handled at once, you will likely need to access IRBNet at another time once you receive notification that everyone has signed the package. Sign back into your IRBNet account.
24. You can select your project from the list after signing in.
25. Look again to the "**Project Administration**" section and select "**Submit this package**."



26. The page below will appear. You want to be sure to select "**Ball State University IRB, Muncie, IN**." Once this is highlighted, click "**Continue**."


IRBNet supports multiple models of review. Using the IRBNet "Submit" feature, you may electronically submit this document package to either a single Board, or to multiple Boards. Each Board you submit to will be notified of your submission and given access to view your electronic documents. Each Board will also be permitted to electronically record their review decision, which will be stored as a permanent part of your project record. You will be automatically notified when the review decision is electronically recorded.
Please select a Board:
Search for an Organization
Search
Clear
Select a Board *
Arkansas State University IBC, Jonesboro, AR
Arnold Palmer Medical Center (APMC) IRB, Orlando, FL
Aspire IRB, San Diego, CA
Aspirus Wausau Hospital, Wausau, WI
Atlantic Health System, Morristown, NJ
Aultman Health Foundation, Canton, OH
Azusa Pacific University, Azusa, CA
Ball State University IRB, Muncie, IN
Continue
Cancel
* required fields

27. You need to select the submission type, select "**New Project**" from the dropdown box. If you would like to include any comments that will be sent to the reviewers, feel free to do so. Click "**Submit**."

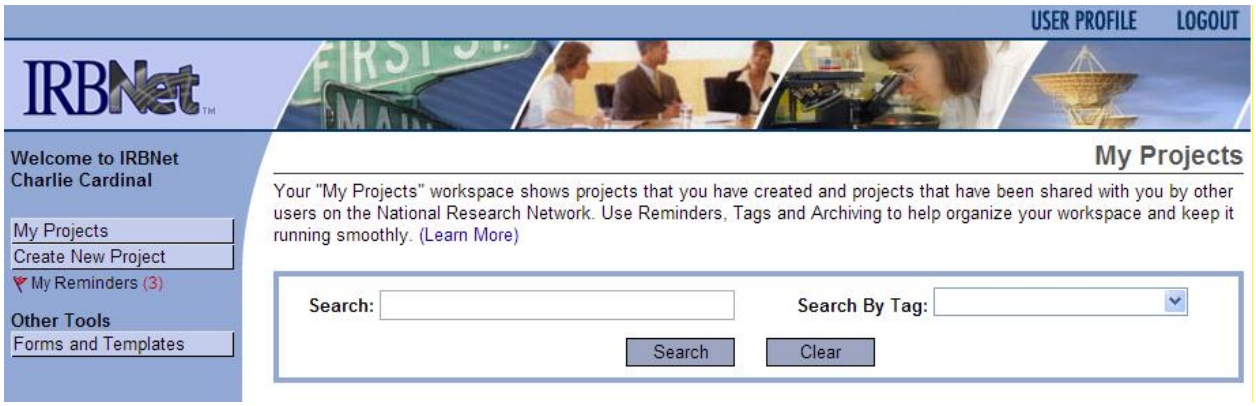
The following IRBNet users at Ball State University IRB will be automatically notified of your submission:
Byers, Bryan
Mangelli, Chris
Mulcahy, John
Weaver, Jennifer
Submission Type: *
You may also specify additional comments to be included in this notification.
Your Comments:
Submit
Cancel

28. The reviewers will now be notified of your submission and the review process can begin. You will receive a time stamp for the submission.

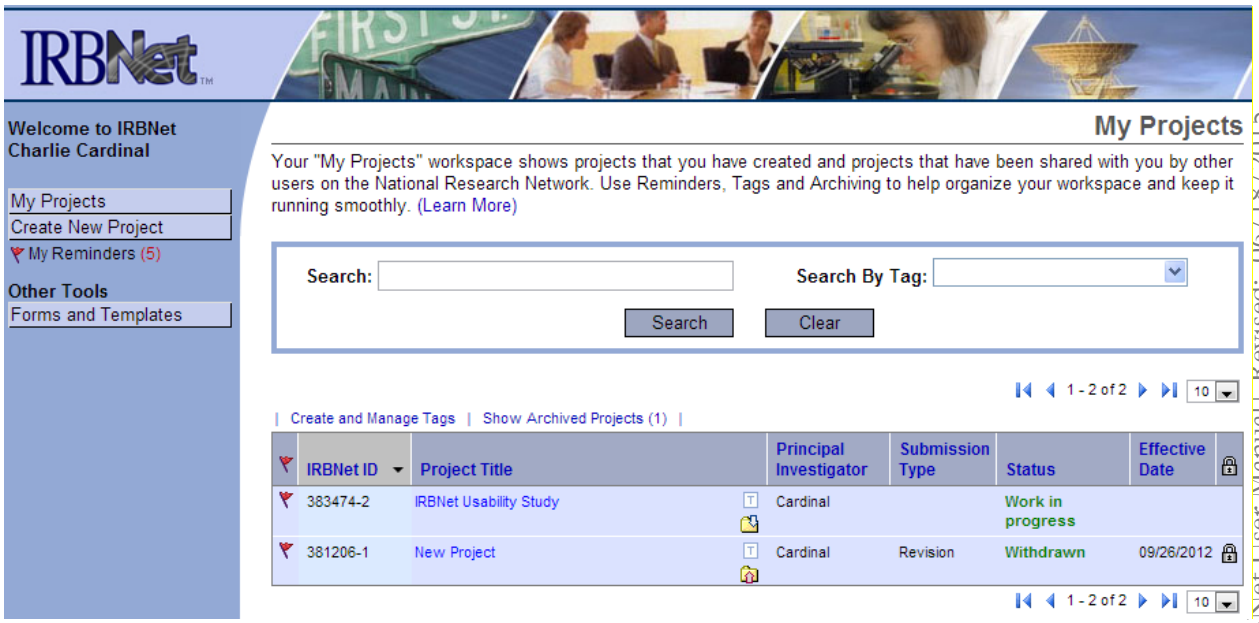
Minor Revisions (Unlock)

Minor modifications may be necessary after the applicable committee has reviewed your initial protocol submission. This section of the user manual will guide principal investigators in the steps necessary to submit minor modifications. You will receive an e-mail indicating that your project has been unlocked and modifications are required.

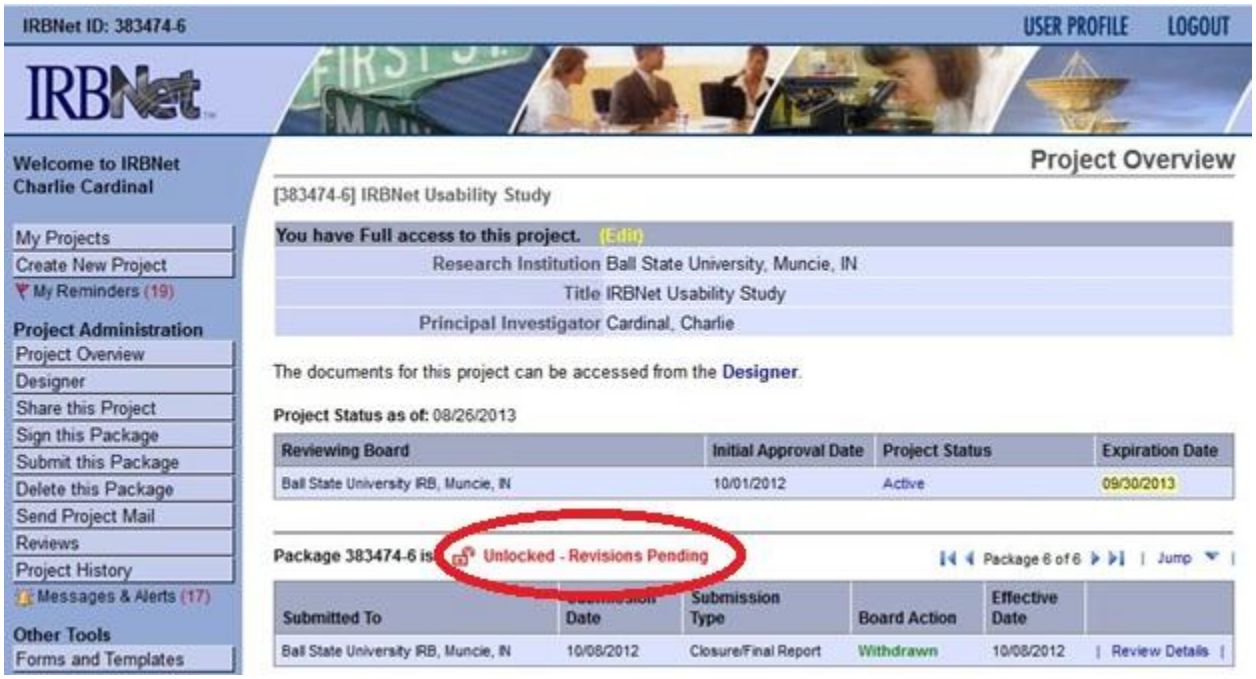
1. Login to www.irbnet.org with your username and password, and then click on the "**My Projects**" button on the left side navigation menu.


USER PROFILE
LOGOUT
IRBNet
Welcome to IRBNet
Charlie Cardinal
My Projects
Create New Project
My Reminders (3)
Other Tools
Forms and Templates
My Projects
Your "My Projects" workspace shows projects that you have created and projects that have been shared with you by other users on the National Research Network. Use Reminders, Tags and Archiving to help organize your workspace and keep it running smoothly. (Learn More)
Search:
Search By Tag:
Search
Clear

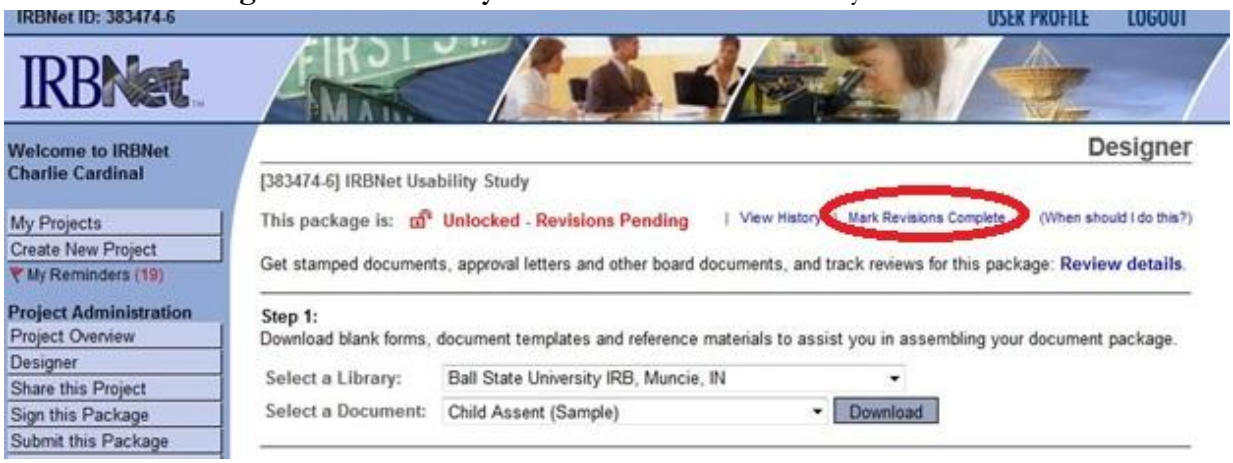
2. Select the project you wish to modify.



3. Click on **"Unlocked – Revisions Pending"** in red to the right of the Package number. On the next screen you will complete the requested changes.



4. Once the changes are made, click on **"Mark Revisions Complete"** to the right of **Unlocked – Revisions Pending** and **View History** to resubmit the revised study.

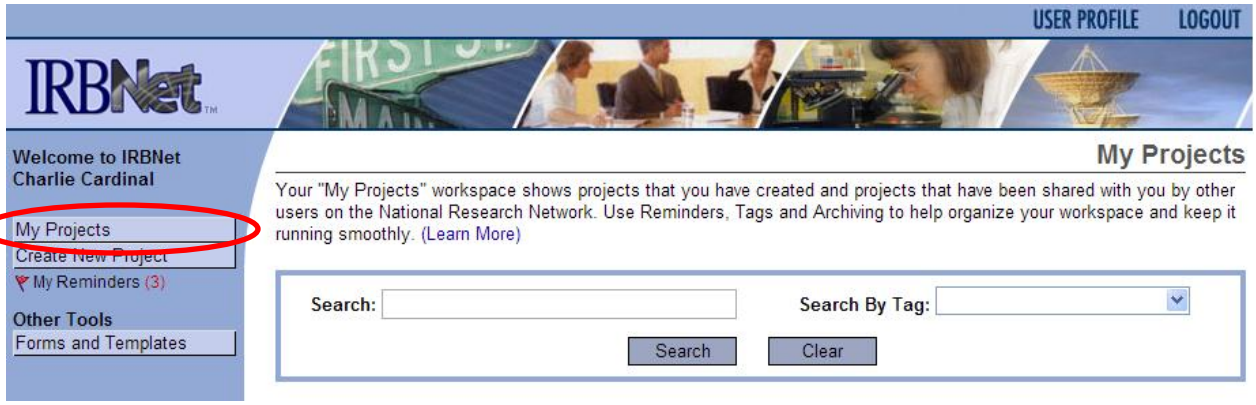


5. After you have locked your submission, reply to the e-mail you received from a member of the Office of Research Integrity to let them know you have made the requested changes.

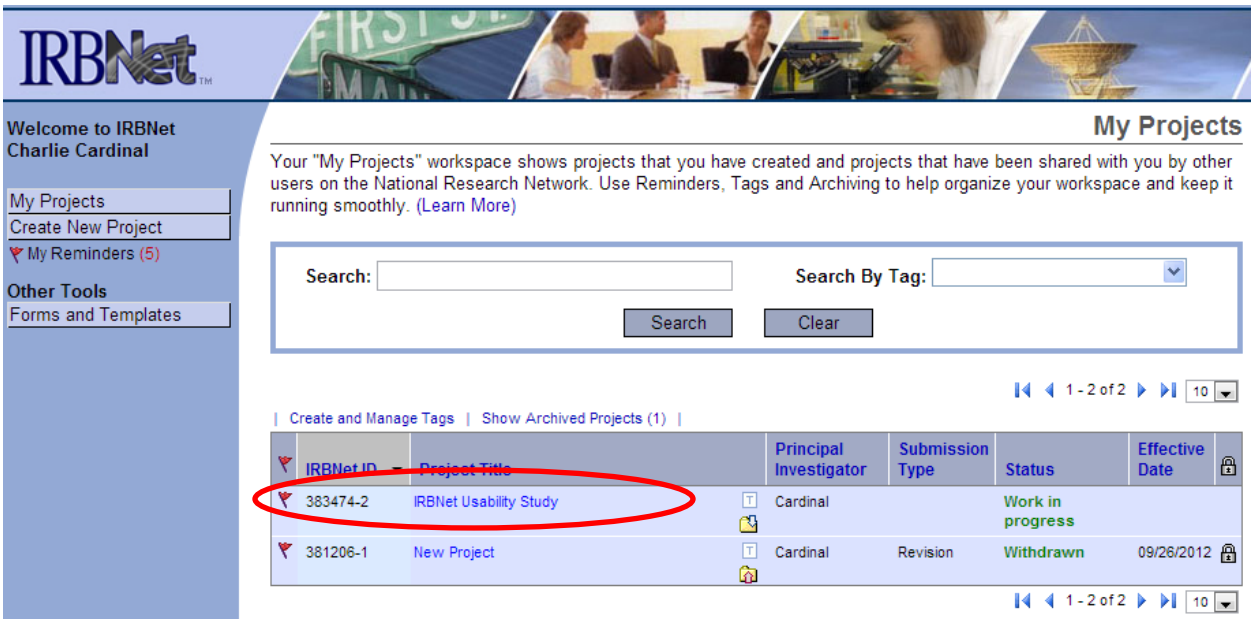
Modification Submission (deferred letter)

Modifications may be necessary after the Institutional Review Board has reviewed your initial protocol submission. This section of the user manual will guide principal investigators in the steps necessary to submit modifications. You will receive an e-mail from the IRB Chair indicating that **"Modifications are Required".**

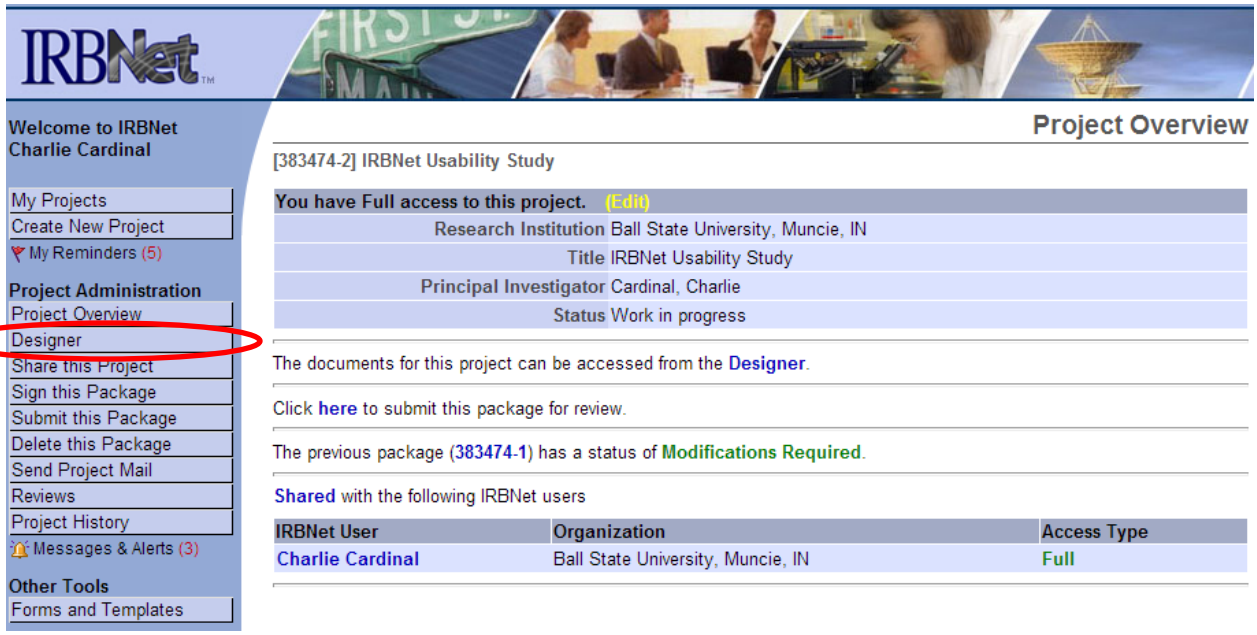
1. Login to www.irbnet.org with your user name and password, and then click on the **"My Projects"** button on the left side navigation menu.


USER PROFILE
LOGOUT
IRBNet
Welcome to IRBNet
Charlie Cardinal
My Projects
Create New Project
My Reminders (3)
Other Tools
Forms and Templates
My Projects
Your "My Projects" workspace shows projects that you have created and projects that have been shared with you by other users on the National Research Network. Use Reminders, Tags and Archiving to help organize your workspace and keep it running smoothly. (Learn More)
Search:
Search By Tag:
Search
Clear

2. Select the project that you wish to modify.



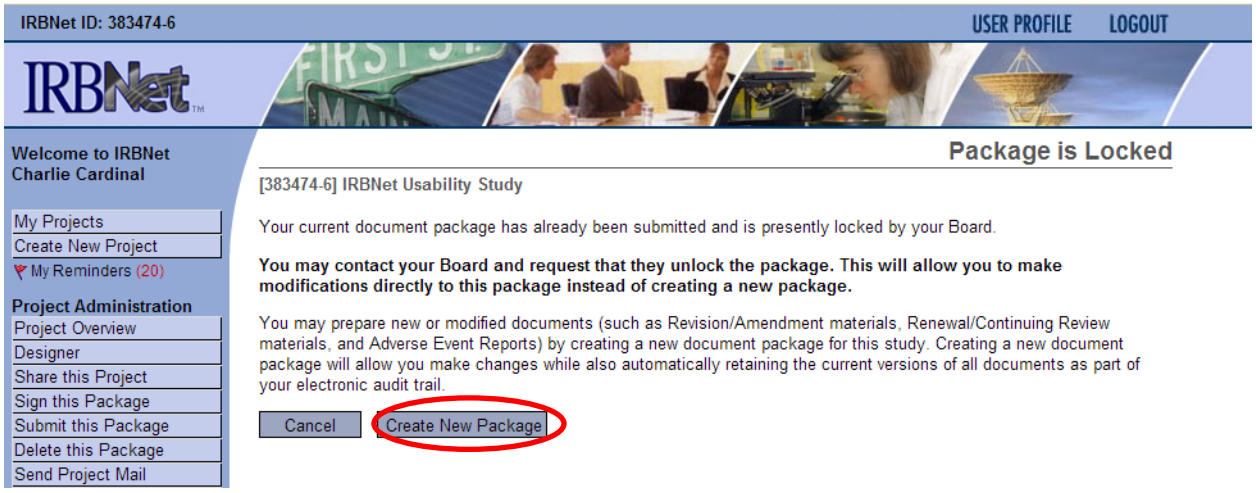
3. The screen below will appear, click on **"Designer"** under the "Project Administration" tab on the left side of the page.



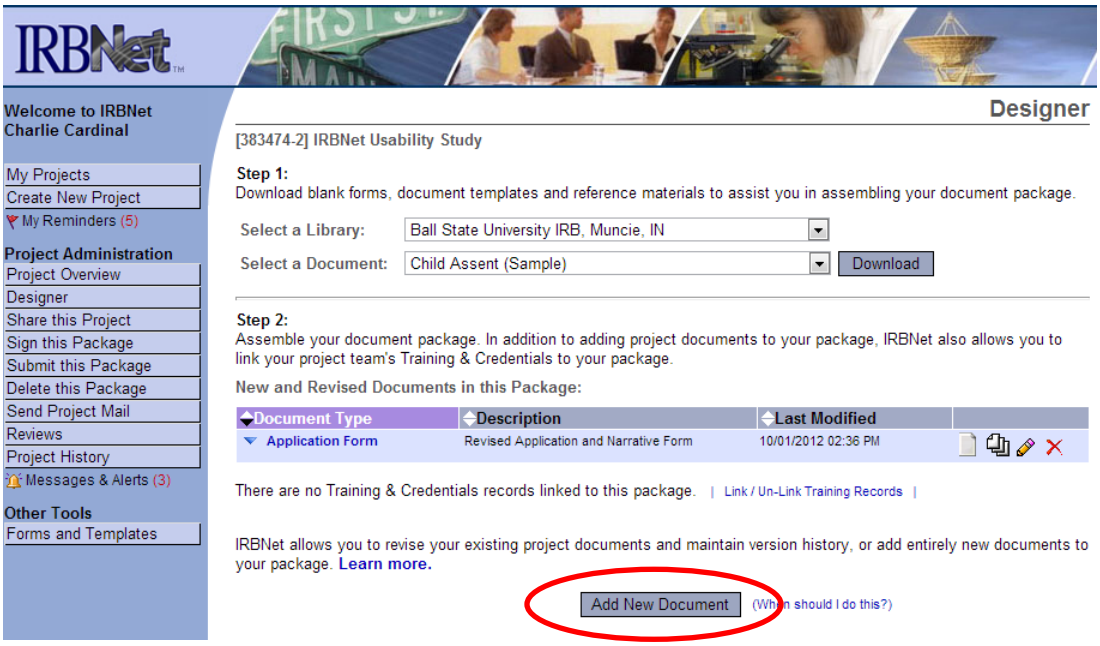
4. Click **"Add New Document"** to submit a revised document with requested changes (Note: changes should be made according to the deferral letter sent to the IRBNet e-mail address you provided).

Add New Document
(When should I do this?)
OR
Documents from Previous Packages that you can Revise: (When should I do this?)
Pkg #
Document Type
Description
Last Modified
Pkg Submission Date
Pkg Status
1 Application Form Application and Narrative Form 10/01/2012 01:44 PM 10/01/2012 Modifications Required
1 Confidentiality/Non-Disclosure Confidentiality and non-disclosure statement 10/01/2012 01:46 PM 10/01/2012 Modifications Required
1 Consent Form Informed Consent Letter 10/01/2012 01:45 PM 10/01/2012 Modifications Required
Copyright © 2002-2012 Research Dataware. All Rights Reserved.

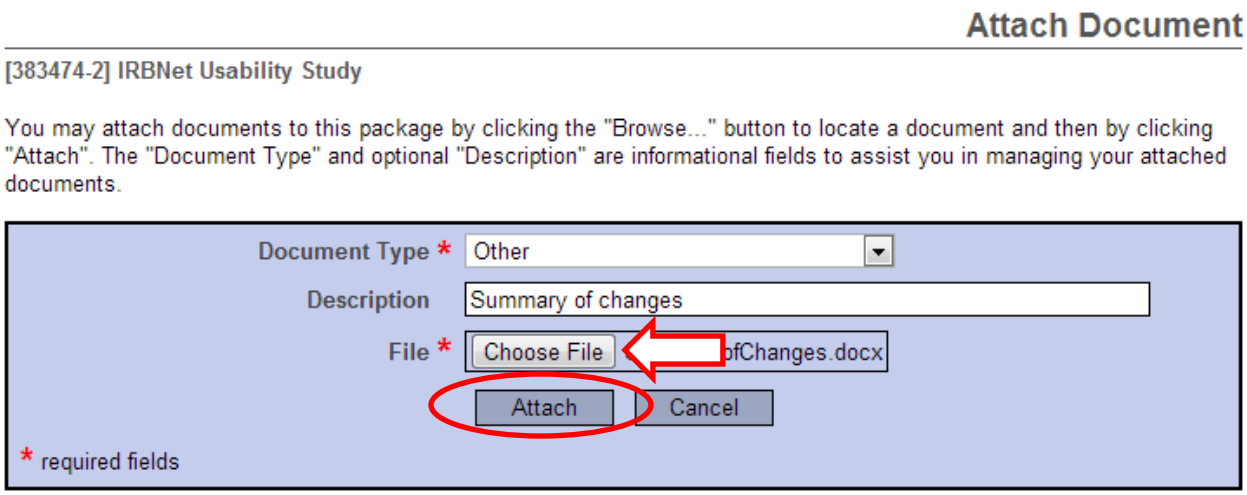
5. Your project will be locked and you will be unable to edit documents that have already been submitted. Click **"Create New Package"** to submit a revised version of the documents requested.


IRBNet ID: 383474-6
USER PROFILE
LOGOUT
IRBNet
Welcome to IRBNet
Charlie Cardinal
My Projects
Create New Project
My Reminders (20)
Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Package is Locked
[383474-6] IRBNet Usability Study
Your current document package has already been submitted and is presently locked by your Board.
You may contact your Board and request that they unlock the package. This will allow you to make modifications directly to this package instead of creating a new package.
You may prepare new or modified documents (such as Revision/Amendment materials, Renewal/Continuing Review materials, and Adverse Event Reports) by creating a new document package for this study. Creating a new document package will allow you make changes while also automatically retaining the current versions of all documents as part of your electronic audit trail.
Cancel
Create New Package

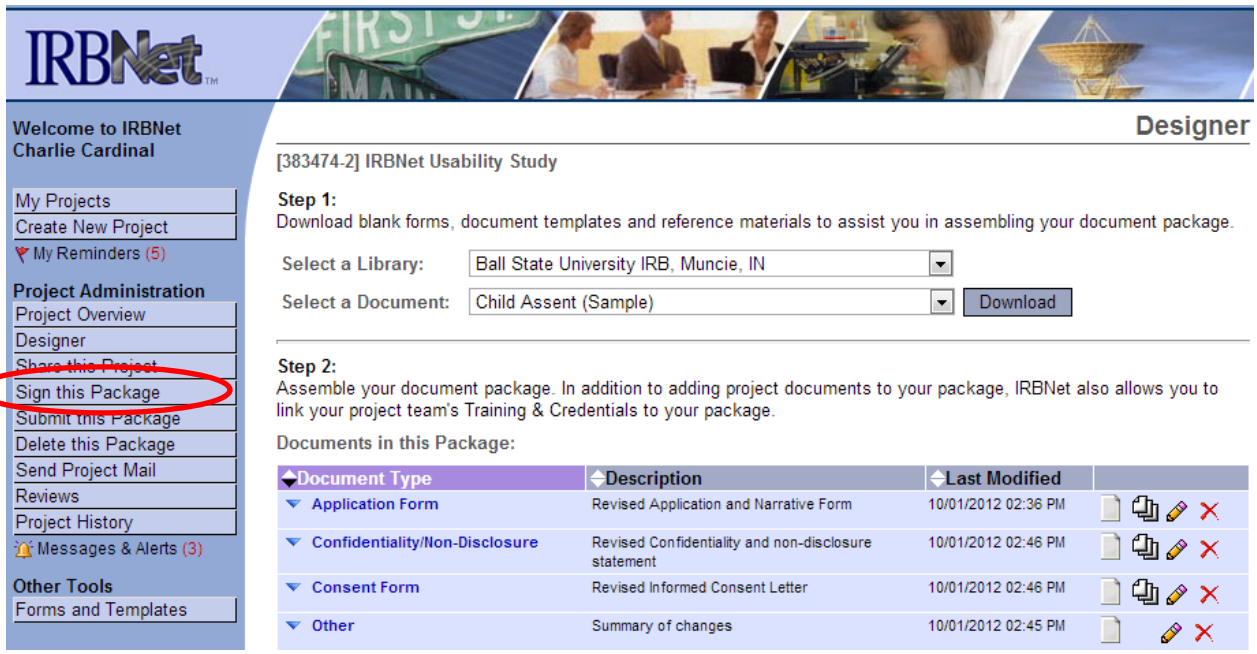
6. Create, complete, and submit the appropriate documents. Reviewers will be interested in seeing changes that you have made from your original document. For minor changes, (e.g., grammatical changes), simply highlighting the change in the new document is sufficient. However, larger changes require a new document to be uploaded in its place.


IRBNet
Welcome to IRBNet
Charlie Cardinal
My Projects
Create New Project
My Reminders (5)
Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Reviews
Project History
Messages & Alerts (3)
Other Tools
Forms and Templates
Designer
[383474-2] IRBNet Usability Study
Step 1:
Download blank forms, document templates and reference materials to assist you in assembling your document package.
Select a Library:
Ball State University IRB, Muncie, IN
Select a Document:
Child Assent (Sample)
Download
Step 2:
Assemble your document package. In addition to adding project documents to your package, IRBNet also allows you to link your project team's Training & Credentials to your package.
New and Revised Documents in this Package:
Document Type
Description
Last Modified
Application Form
Revised Application and Narrative Form
10/01/2012 02:36 PM
There are no Training & Credentials records linked to this package.
Link / Un-Link Training Records
IRBNet allows you to revise your existing project documents and maintain version history, or add entirely new documents to your package.
Learn more.
Add New Document
(When should I do this?)

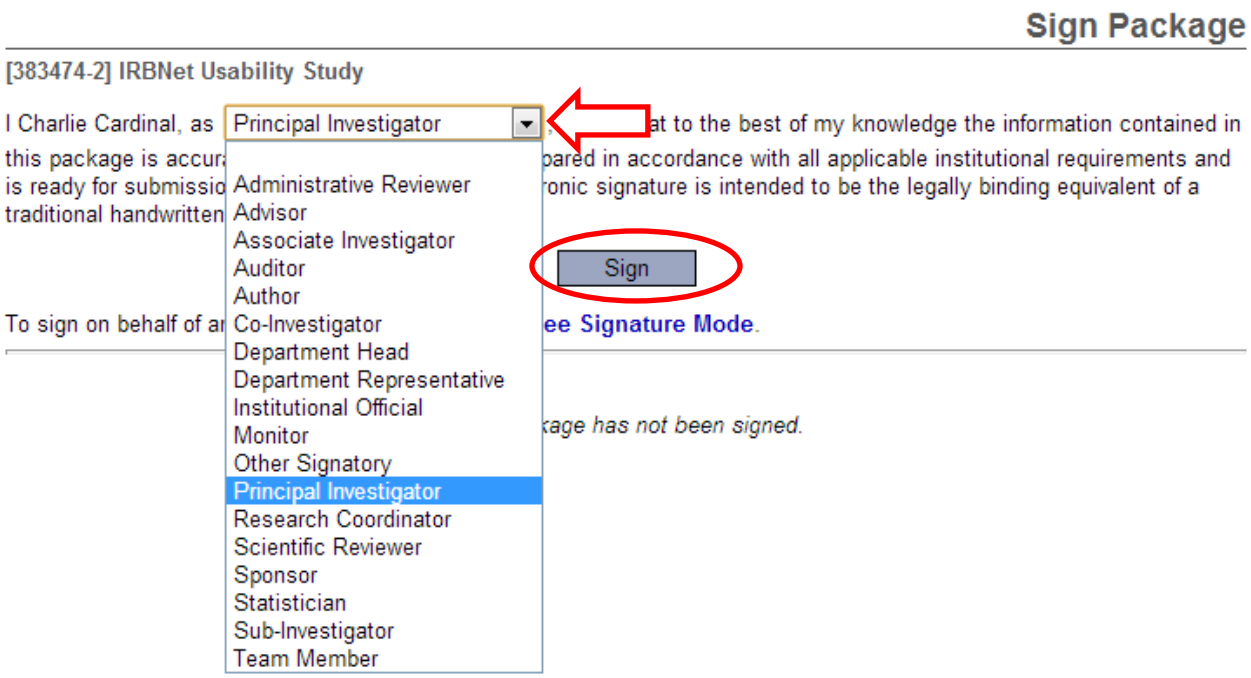
7. In the document type menu, select the most appropriate match for the document you are uploading. If there is no match, select **"Other"** from the menu. Select the **"Choose File"** tab to browse your computer for desired file (arrow). Click the **"Attach"** button to upload the file to your package.


Attach Document
[383474-2] IRBNet Usability Study
You may attach documents to this package by clicking the "Browse..." button to locate a document and then by clicking "Attach". The "Document Type" and optional "Description" are informational fields to assist you in managing your attached documents.
Document Type *
Other
Description
Summary of changes
File *
Choose File
bfChanges.docx
Attach
Cancel
* required fields

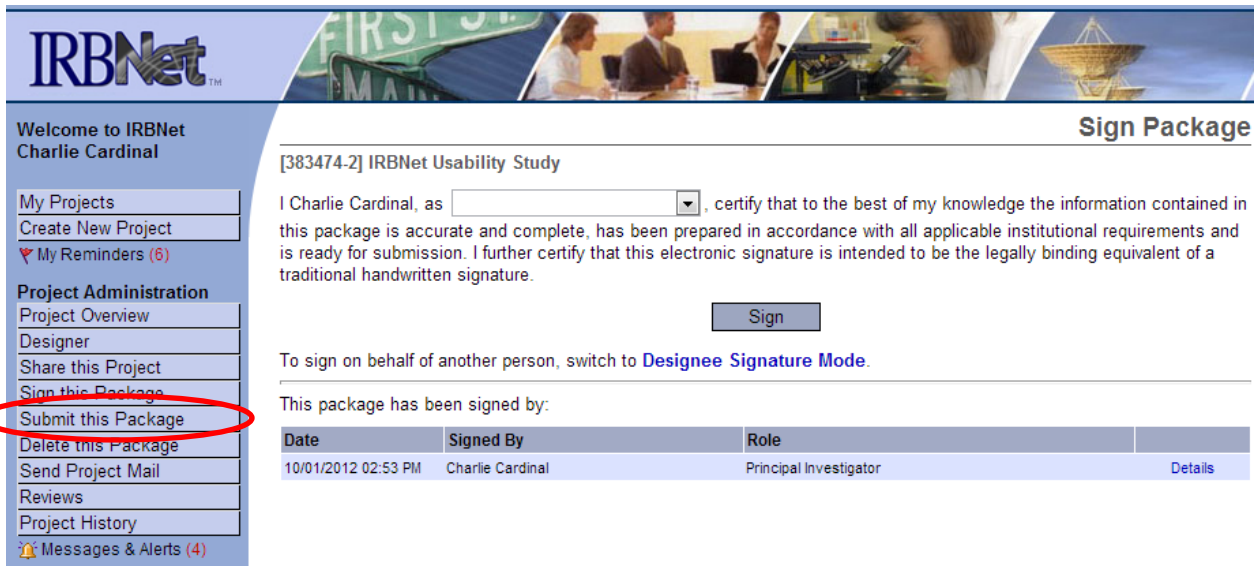
8. Click the **"Sign this Package"** under the **Project Administration** menu on the left.



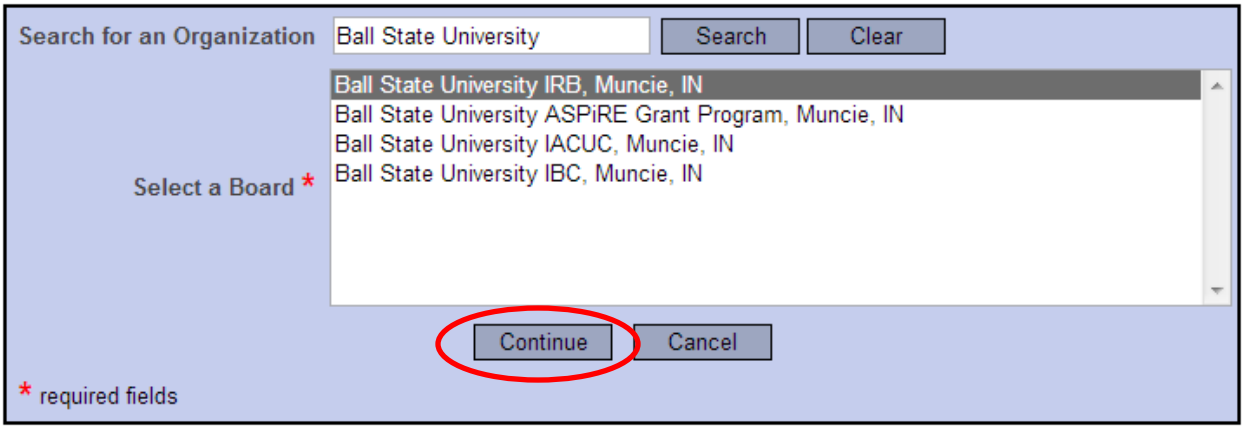
9. Once at the **"Sign Package"** screen, indicate your **project role** (arrow) and click **"Sign".**



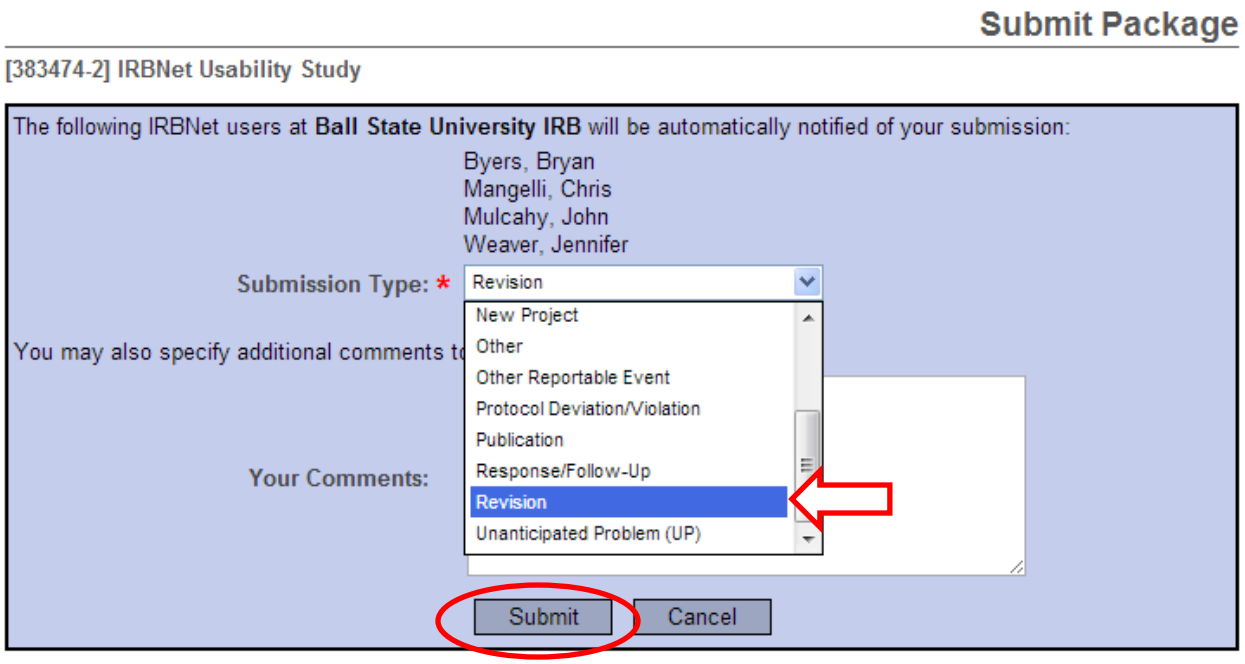
10. Your project is now ready to submit, click **"Submit this Package"** under the **Project Administration** menu.


IRBNet
Welcome to IRBNet
Charlie Cardinal
My Projects
Create New Project
My Reminders (6)
Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Reviews
Project History
Messages & Alerts (4)
Sign Package
[383474-2] IRBNet Usability Study
I Charlie Cardinal, as , certify that to the best of my knowledge the information contained in this package is accurate and complete, has been prepared in accordance with all applicable institutional requirements and is ready for submission. I further certify that this electronic signature is intended to be the legally binding equivalent of a traditional handwritten signature.
Sign
To sign on behalf of another person, switch to Designee Signature Mode.
This package has been signed by:
Date
Signed By
Role
10/01/2012 02:53 PM
Charlie Cardinal
Principal Investigator
Details

11. Search for and select the proper review body at Ball State University (IRB, IACUC, IBC) and click **"Continue".**

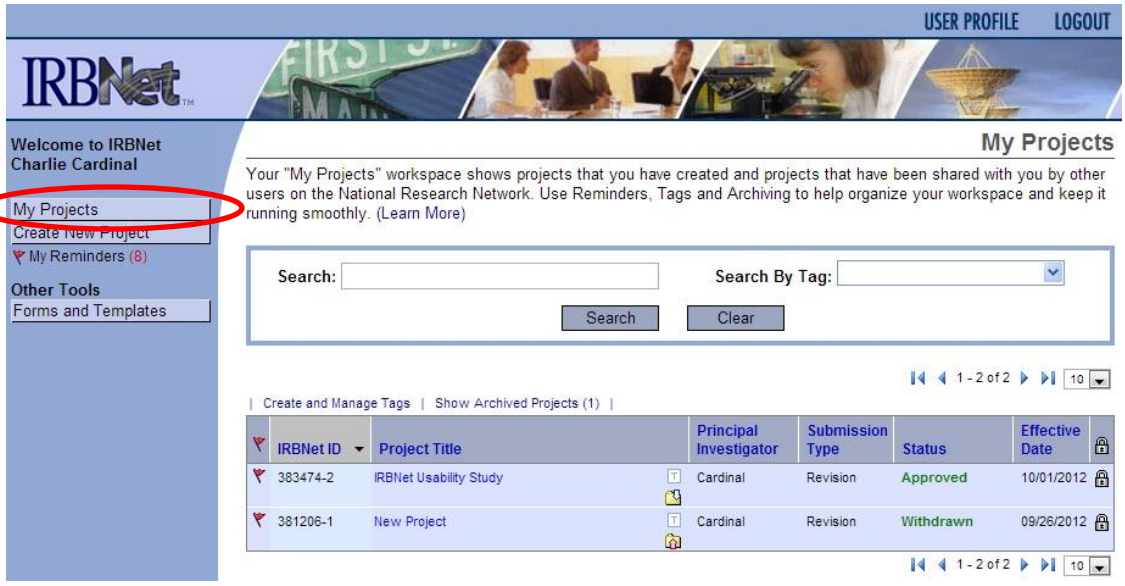


12. Select **"Revision"** for **Submission Type** (arrow), and then click **"Submit".**

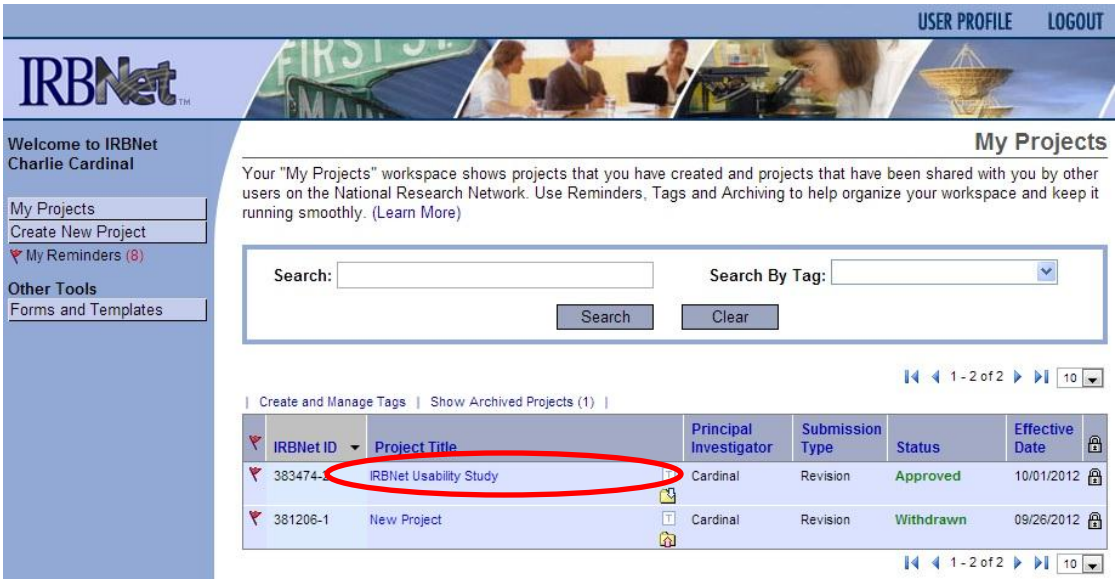


Modifying an Approved Study

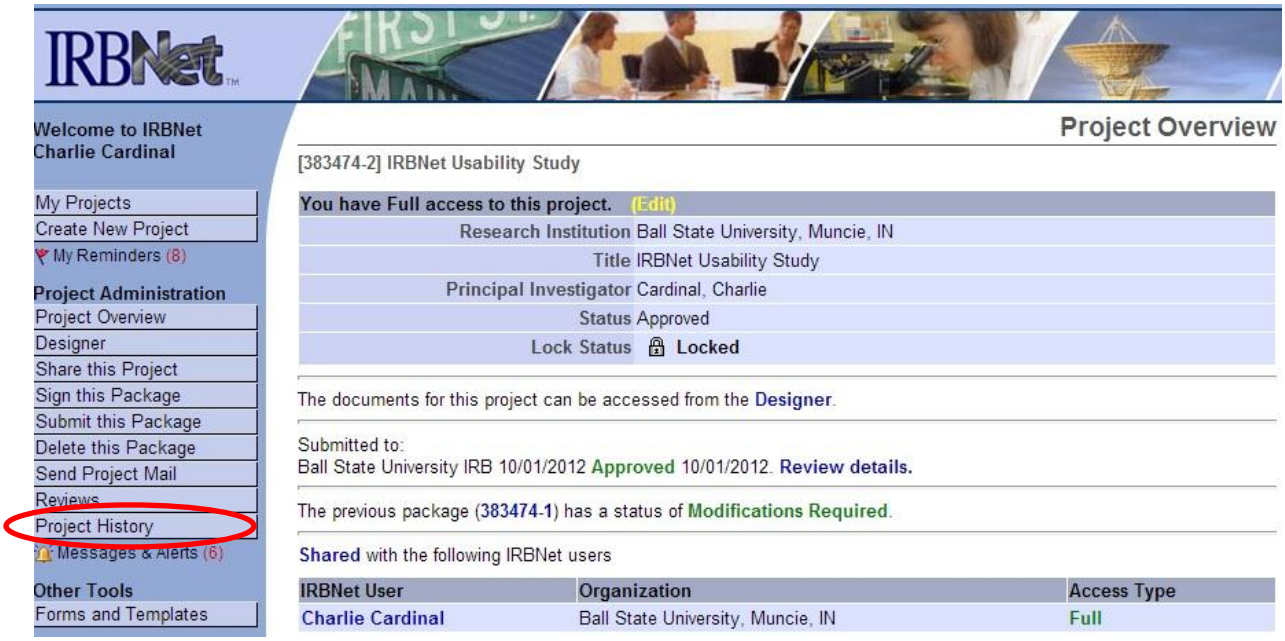
1. Login to www.irbnet.org using your username and password.
2. Select **"My Projects"** on the left side of the screen.



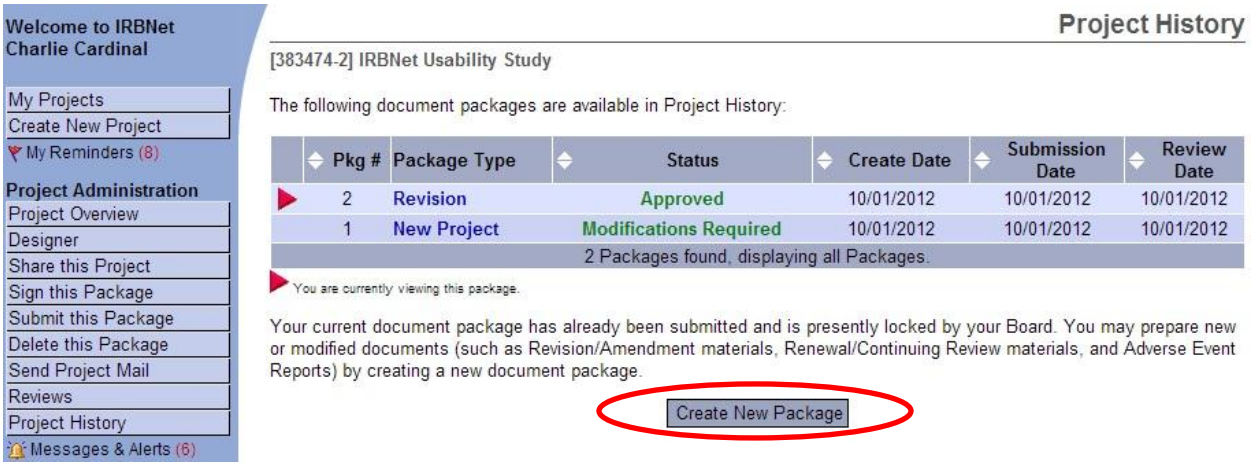
3. Select the project that you want to modify.



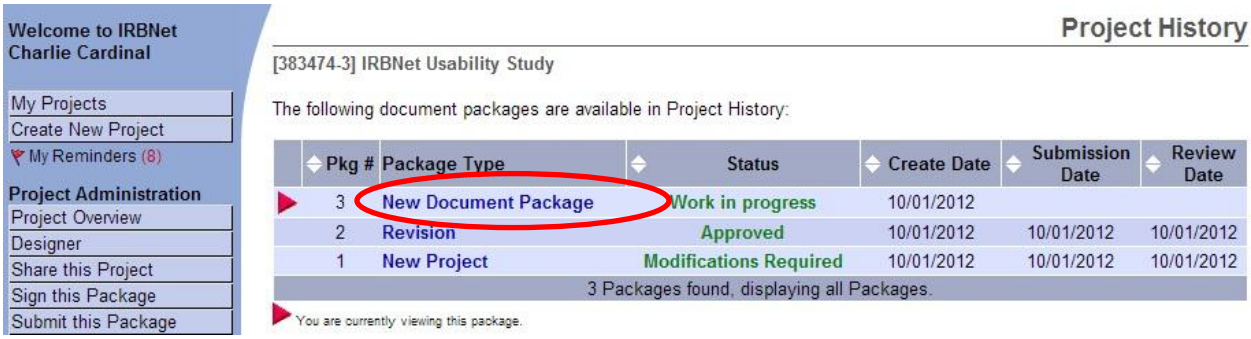
4. Click on **"Project History"** under the **Project Administration** menu.



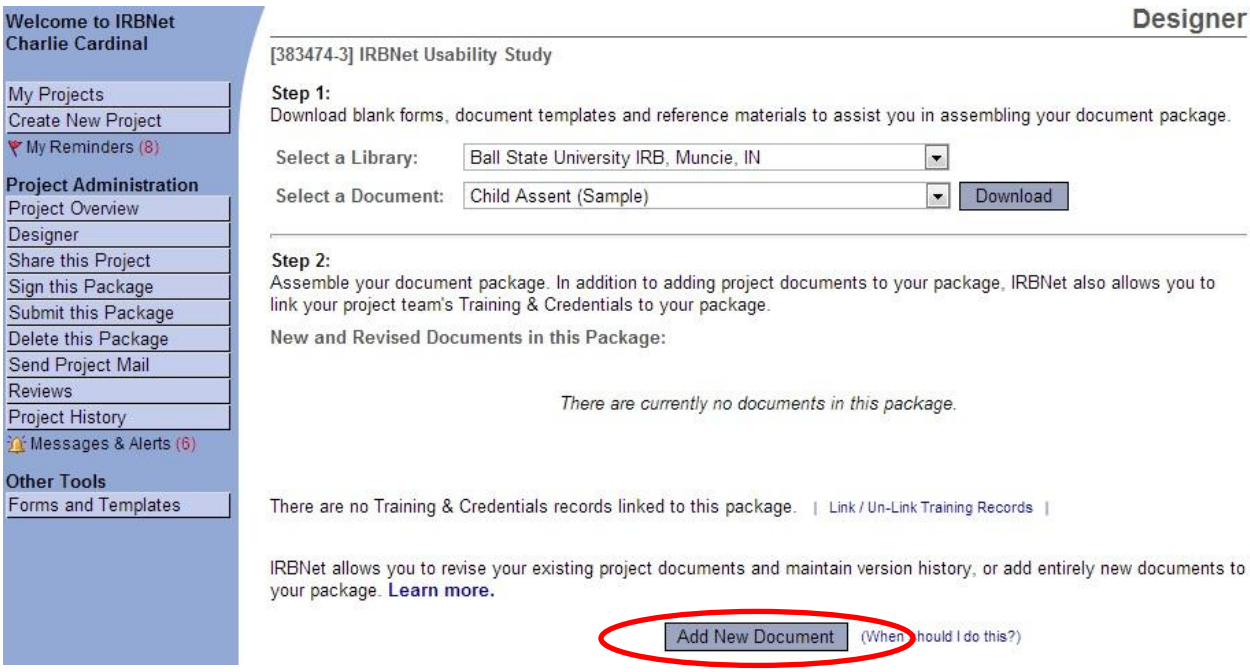
5. Click **"Create New Package"** at the bottom of the page.


Welcome to IRBNet
Charlie Cardinal
My Projects
Create New Project
My Reminders (8)
Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Reviews
Project History
Messages & Alerts (6)
Project History
[383474-2] IRBNet Usability Study
The following document packages are available in Project History:
Pkg #
Package Type
Status
Create Date
Submission Date
Review Date
2 Revision Approved 10/01/2012 10/01/2012 10/01/2012
1 New Project Modifications Required 10/01/2012 10/01/2012 10/01/2012
2 Packages found, displaying all Packages.
You are currently viewing this package.
Your current document package has already been submitted and is presently locked by your Board. You may prepare new or modified documents (such as Revision/Amendment materials, Renewal/Continuing Review materials, and Adverse Event Reports) by creating a new document package.
Create New Package

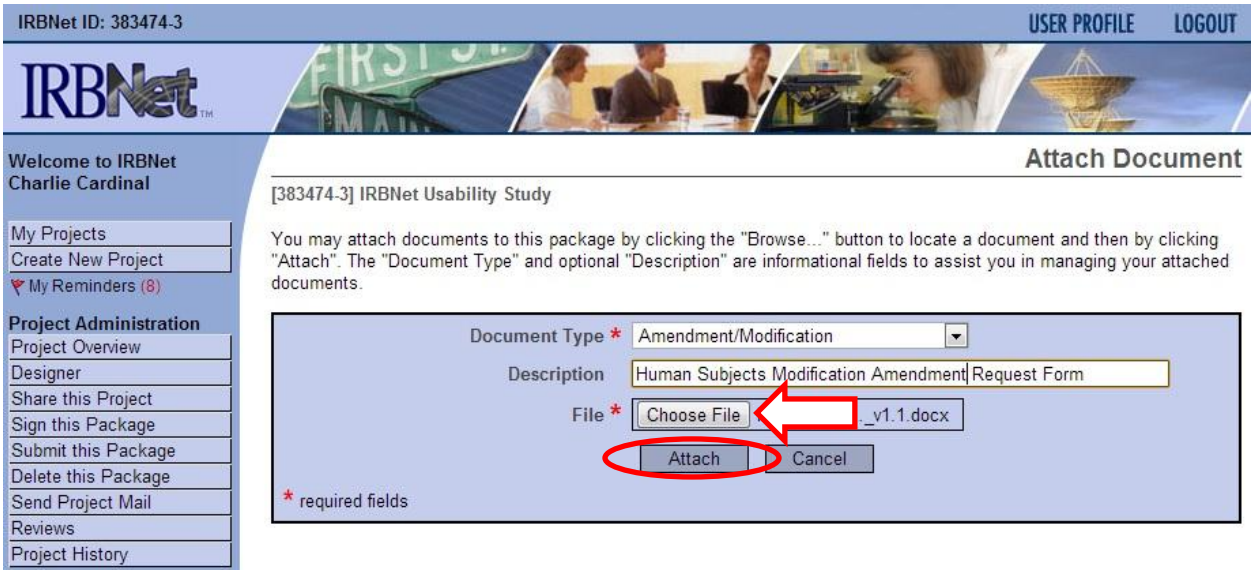
6. **"New Document Package"** will appear, click this to be taken to the **Designer** page.


Welcome to IRBNet
Charlie Cardinal
My Projects
Create New Project
My Reminders (8)
Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Project History
[383474-3] IRBNet Usability Study
The following document packages are available in Project History:
Pkg # Package Type Status Create Date Submission Date Review Date
3 New Document Package Work in progress 10/01/2012
2 Revision Approved 10/01/2012 10/01/2012 10/01/2012
1 New Project Modifications Required 10/01/2012 10/01/2012 10/01/2012
3 Packages found, displaying all Packages.
You are currently viewing this package.

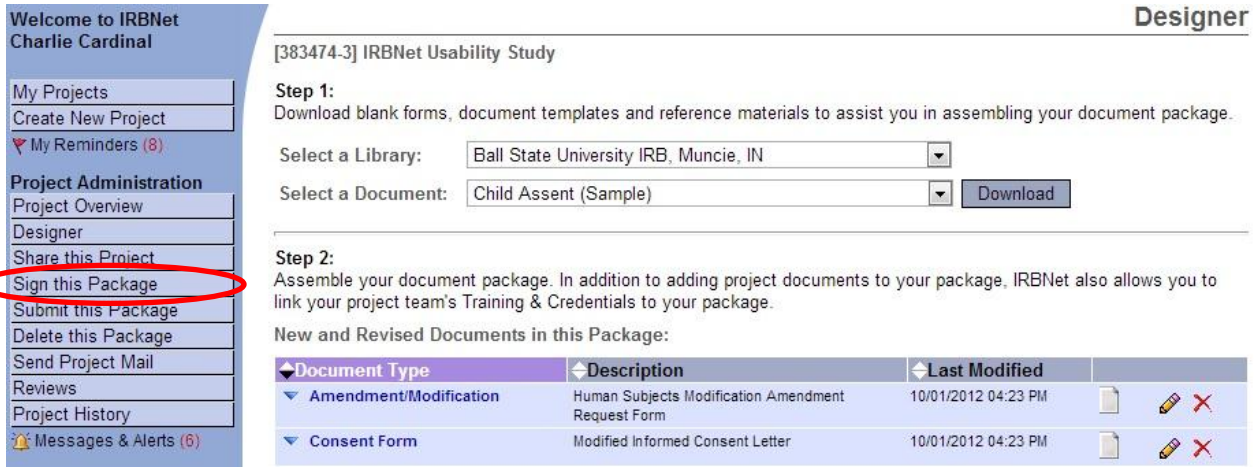
7. Fill out and complete the **IRB Modification/Amendment Form**.
    a. This can be obtained in the "Forms and Templates" section of IRBNet.
8. Prepare any additional relevant project documents indicated in the IRB Modification/Amendment Form. This could include: Informed consent documents, parental submission documents, surveys, recruitment letters or e-mails, introductory scripts, and any additional documentation that will assist the committee in understanding the changes you are making to the study. <u>All changes must be highlighted, otherwise your study won't be reviewed.</u>
9. Click **"Add New Document"** near the middle of the screen.


Welcome to IRBNet
Charlie Cardinal
My Projects
Create New Project
My Reminders (8)
Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Reviews
Project History
Messages & Alerts (6)
Other Tools
Forms and Templates
Designer
[383474-3] IRBNet Usability Study
Step 1:
Download blank forms, document templates and reference materials to assist you in assembling your document package.
Select a Library: Ball State University IRB, Muncie, IN
Select a Document: Child Assent (Sample)
Download
Step 2:
Assemble your document package. In addition to adding project documents to your package, IRBNet also allows you to link your project team's Training & Credentials to your package.
New and Revised Documents in this Package:
There are currently no documents in this package.
There are no Training & Credentials records linked to this package. | Link / Un-Link Training Records |
IRBNet allows you to revise your existing project documents and maintain version history, or add entirely new documents to your package. Learn more.
Add New Document
(When should I do this?)

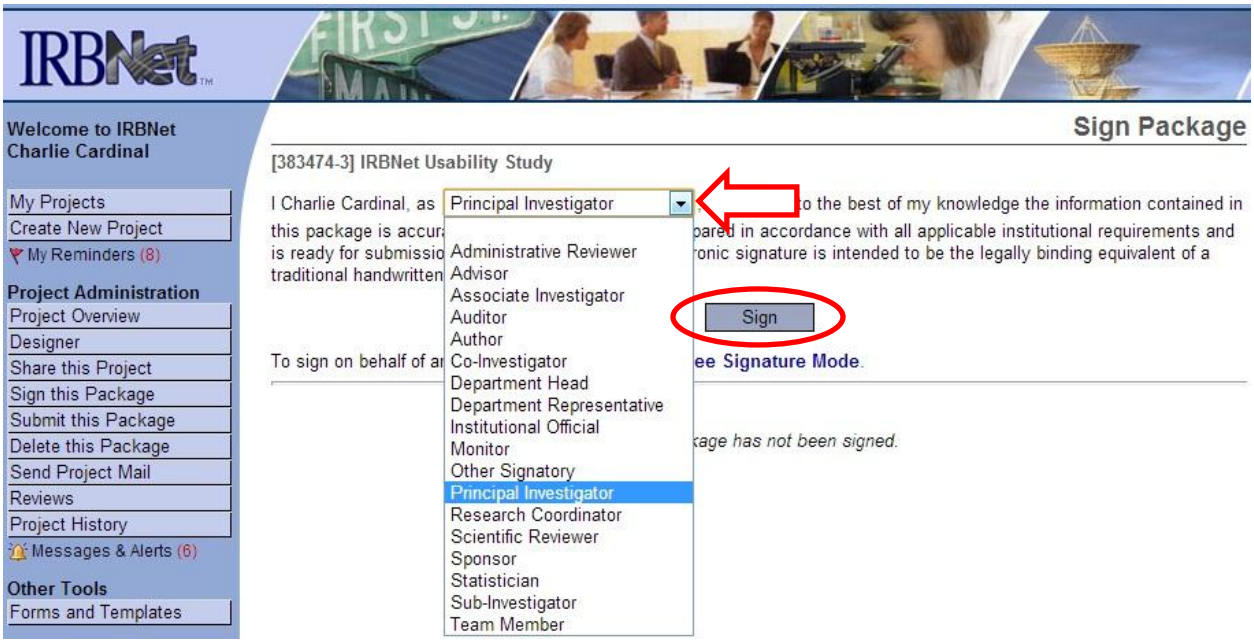
10. In the Document Type box, select the category the bests matches the document you are uploading. If you are uploading the modification amendment form, select **"Amendment/Modification"**. If you are uploading supporting documentation, pick the best match. If there is no match select "other". Click **"Choose File"** (arrow) to browse your computer for the desired file. Once found, click **"Attach"** to upload the file to your package.



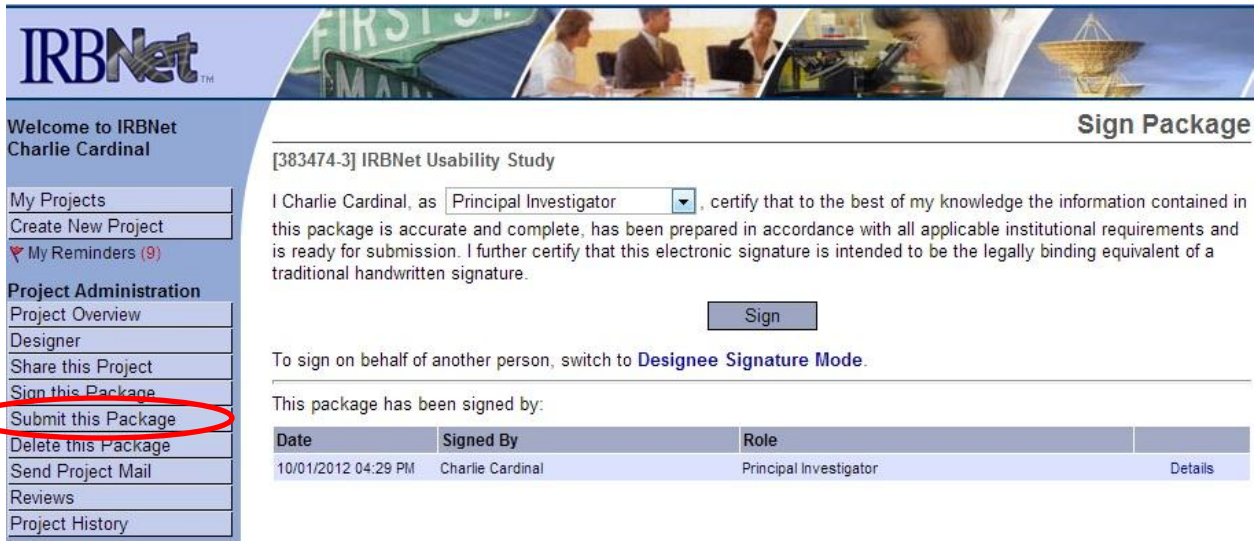
11. **Repeat steps 9 and 10 for all additional supporting documents** until they have been added to your package.
12. Click **"Sign this Package"** under the **Project Administration** menu on the left side of the screen.



13. Once at the **Sign Package** screen, indicate your **project role** (arrow) and click **"Sign".**

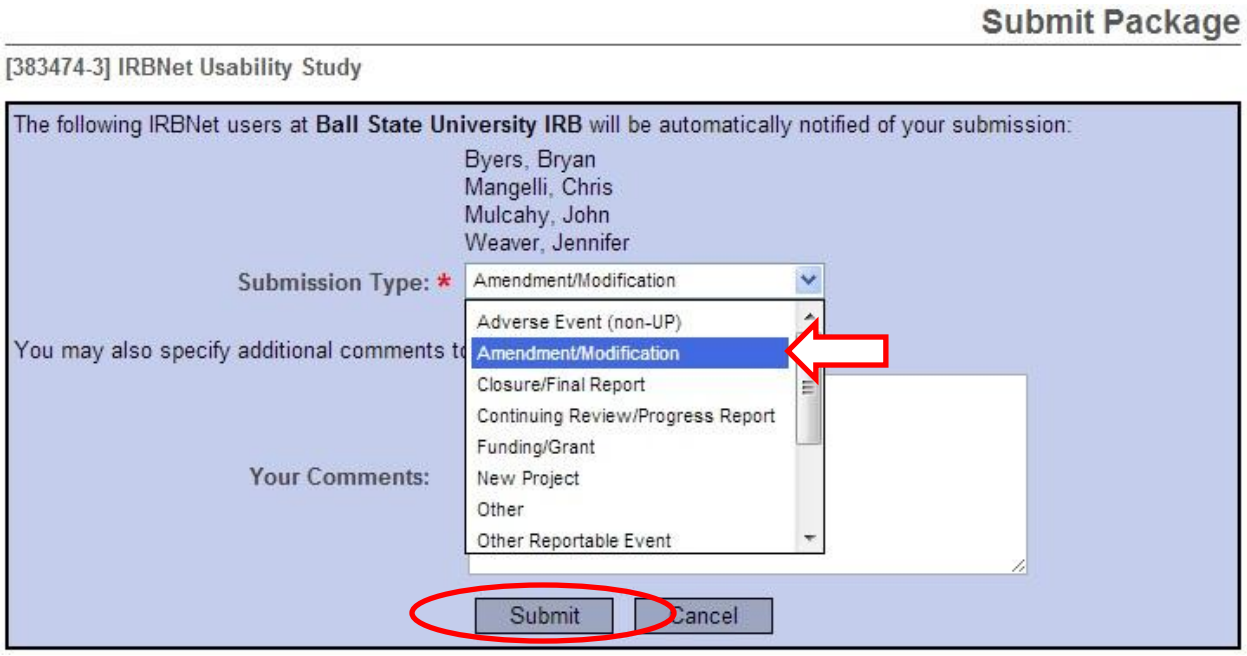


13. Your modification/ amendment is now ready to submit, click **"Submit this Package"** under the **Project Administration** menu.


IRBNet
Welcome to IRBNet
Charlie Cardinal
My Projects
Create New Project
My Reminders (9)
Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Reviews
Project History
Sign Package
[383474-3] IRBNet Usability Study
I Charlie Cardinal, as Principal Investigator, certify that to the best of my knowledge the information contained in this package is accurate and complete, has been prepared in accordance with all applicable institutional requirements and is ready for submission. I further certify that this electronic signature is intended to be the legally binding equivalent of a traditional handwritten signature.
Sign
To sign on behalf of another person, switch to Designee Signature Mode.
This package has been signed by:
Date
Signed By
Role
10/01/2012 04:29 PM
Charlie Cardinal
Principal Investigator
Details

14. Search for and select the proper review body at Ball State University (IRB, IACUC, IBC) and click **"Continue".**

15. Select **"Amendment/Modification"** for **Submission Type** (arrow), and then click **"Submit".**



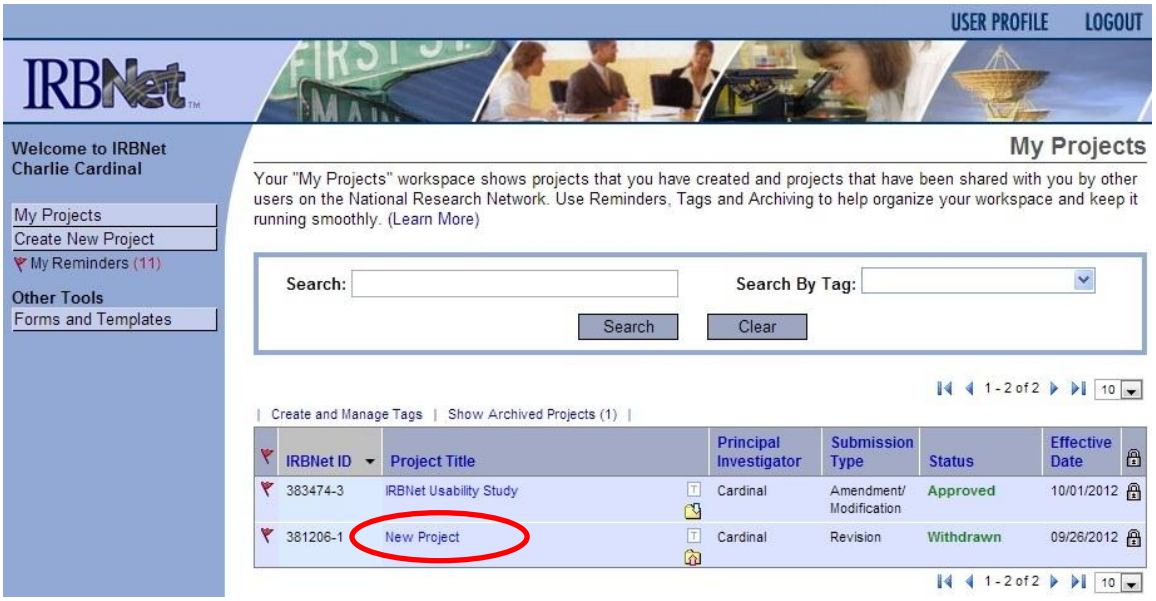
Continuing Review Submission (expedited and full board)

Projects may be approved for one or two years. You will be notified before your project expires. To continue working on a project you must submit and be approved for a continuing review before the expiration date.

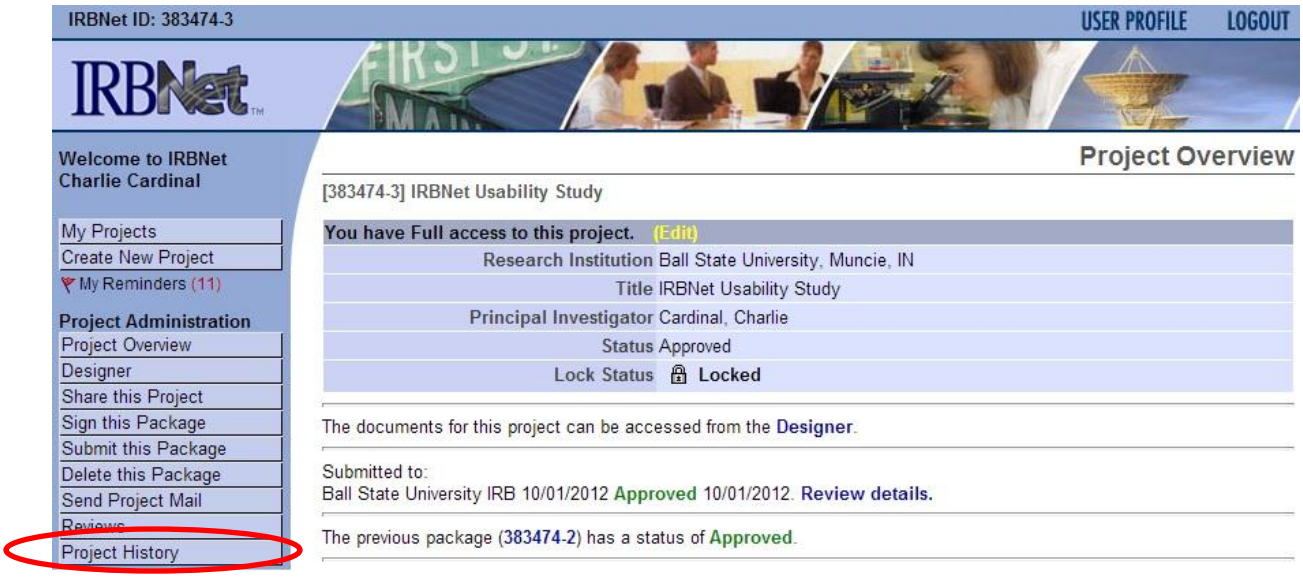
1. Login to www.irbnet.org with your username and password.
2. Select **"My Projects"** on the left side of the screen.

USER PROFILE
LOGOUT
IRBNet
Welcome to IRBNet
Charlie Cardinal
My Projects
Create New Project
My Reminders (11)
Other Tools
Forms and Templates
My Projects
Your "My Projects" workspace shows projects that you have created and projects that have been shared with you by other users on the National Research Network. Use Reminders, Tags and Archiving to help organize your workspace and keep it running smoothly. (Learn More)
Search:
Search By Tag:
Search
Clear
1 - 2 of 2
10

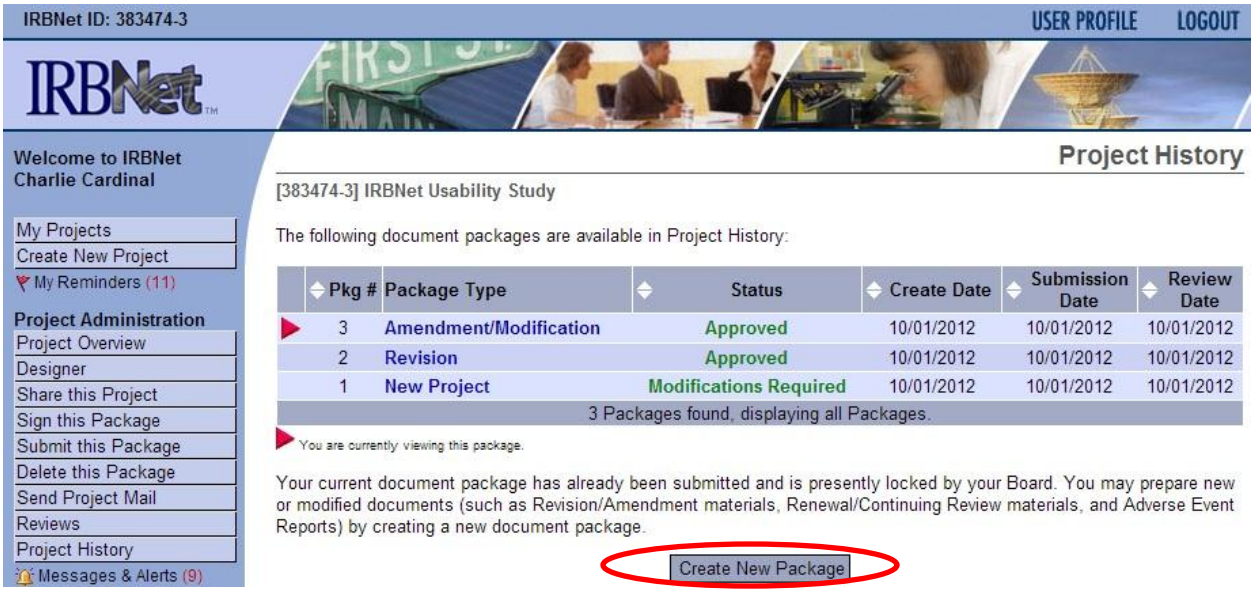
3. Select the project for which you want to submit a continuing review.



4. Select **"Project History"** under the **Project Administration** menu.



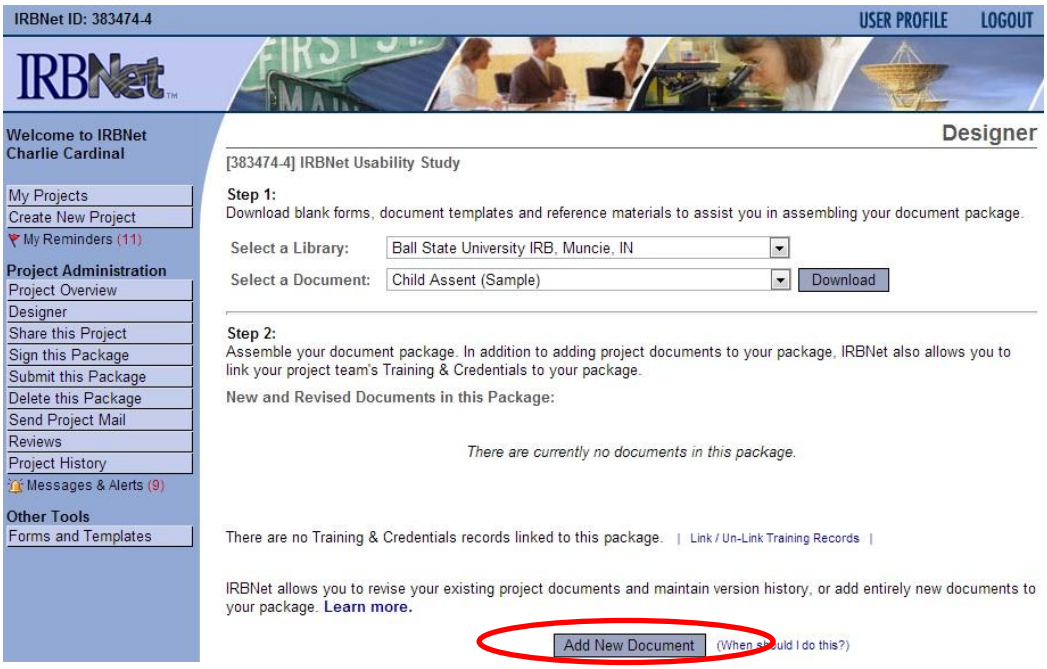
5. Click **"Create New Package"** at the bottom of the page.


IRBNet ID: 383474-3
USER PROFILE
LOGOUT
IRBNet
Welcome to IRBNet
Charlie Cardinal
My Projects
Create New Project
My Reminders (11)
Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Reviews
Project History
Messages & Alerts (9)
Project History
[383474-3] IRBNet Usability Study
The following document packages are available in Project History:
Pkg # Package Type Status Create Date Submission Date Review Date
3 Amendment/Modification Approved 10/01/2012 10/01/2012 10/01/2012
2 Revision Approved 10/01/2012 10/01/2012 10/01/2012
1 New Project Modifications Required 10/01/2012 10/01/2012 10/01/2012
3 Packages found, displaying all Packages.
You are currently viewing this package.
Your current document package has already been submitted and is presently locked by your Board. You may prepare new or modified documents (such as Revision/Amendment materials, Renewal/Continuing Review materials, and Adverse Event Reports) by creating a new document package.
Create New Package

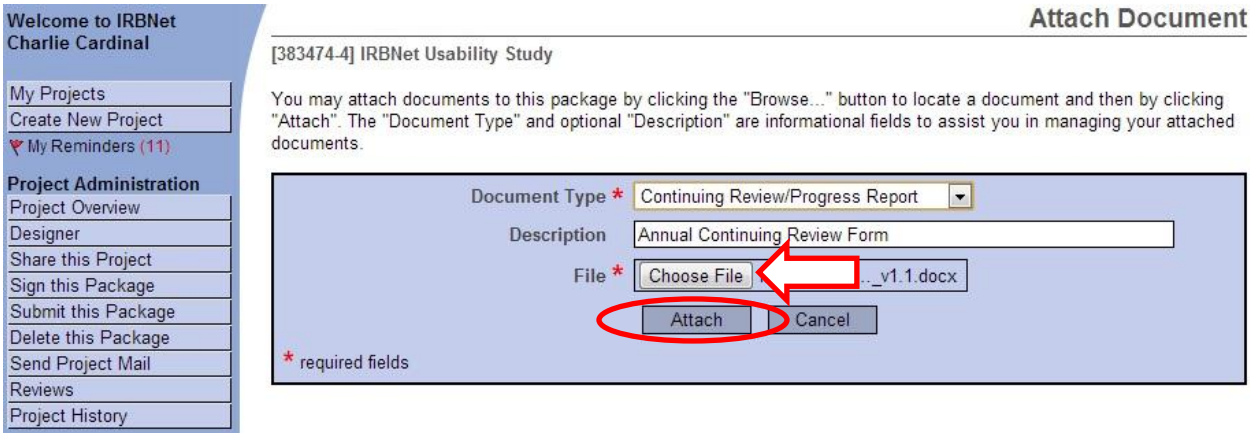
6. **"New Document Package"** will appear, click this to be taken to the **Designer** page.

Welcome to IRBNet
Charlie Cardinal
My Projects
Create New Project
My Reminders (11)
Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Project History
[383474-4] IRBNet Usability Study
The following document packages are available in Project History:
Pkg # | Package Type | Status | Create Date | Submission Date | Review Date
4 | New Document Package | Work in progress | 10/03/2012
3 | Amendment/Modification | Approved | 10/01/2012 | 10/01/2012 | 10/01/2012
2 | Revision | Approved | 10/01/2012 | 10/01/2012 | 10/01/2012
1 | New Project | Modifications Required | 10/01/2012 | 10/01/2012 | 10/01/2012
4 Packages found, displaying all Packages.
You are currently viewing this package.

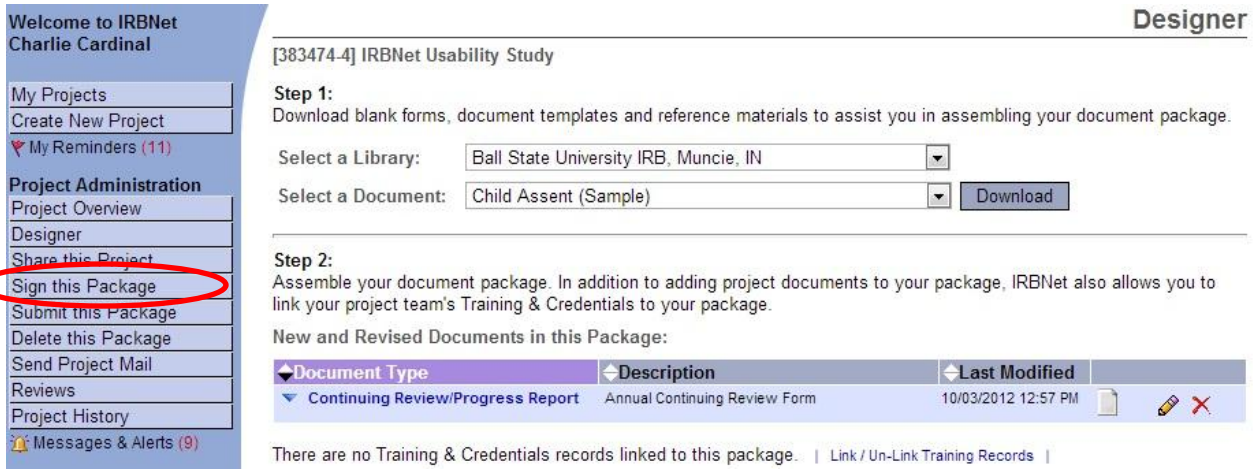
7. Fill out and complete the **IRB Continuing Review form**.
    a. This can be obtained in the Forms and Templates section of IRBNet.
8. If you are making any modifications, you will need to fill out and submit the Human Subjects Modification Amendments Form in addition the Continuing Review Form. You must also include all necessary documentation (see the *Modifying an Approved Study*, page 20, of this manual for instructions).
9. Click **"Add New Document"** near the middle of the screen.


IRBNet ID: 383474-4
USER PROFILE
LOGOUT
IRBNet
Welcome to IRBNet
Charlie Cardinal
My Projects
Create New Project
My Reminders (11)
Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Reviews
Project History
Messages & Alerts (9)
Other Tools
Forms and Templates
Designer
[383474-4] IRBNet Usability Study
Step 1:
Download blank forms, document templates and reference materials to assist you in assembling your document package.
Select a Library: Ball State University IRB, Muncie, IN
Select a Document: Child Assent (Sample)
Download
Step 2:
Assemble your document package. In addition to adding project documents to your package, IRBNet also allows you to link your project team's Training & Credentials to your package.
New and Revised Documents in this Package:
There are currently no documents in this package.
There are no Training & Credentials records linked to this package. | Link / Un-Link Training Records |
IRBNet allows you to revise your existing project documents and maintain version history, or add entirely new documents to your package. Learn more.
Add New Document
(When should I do this?)

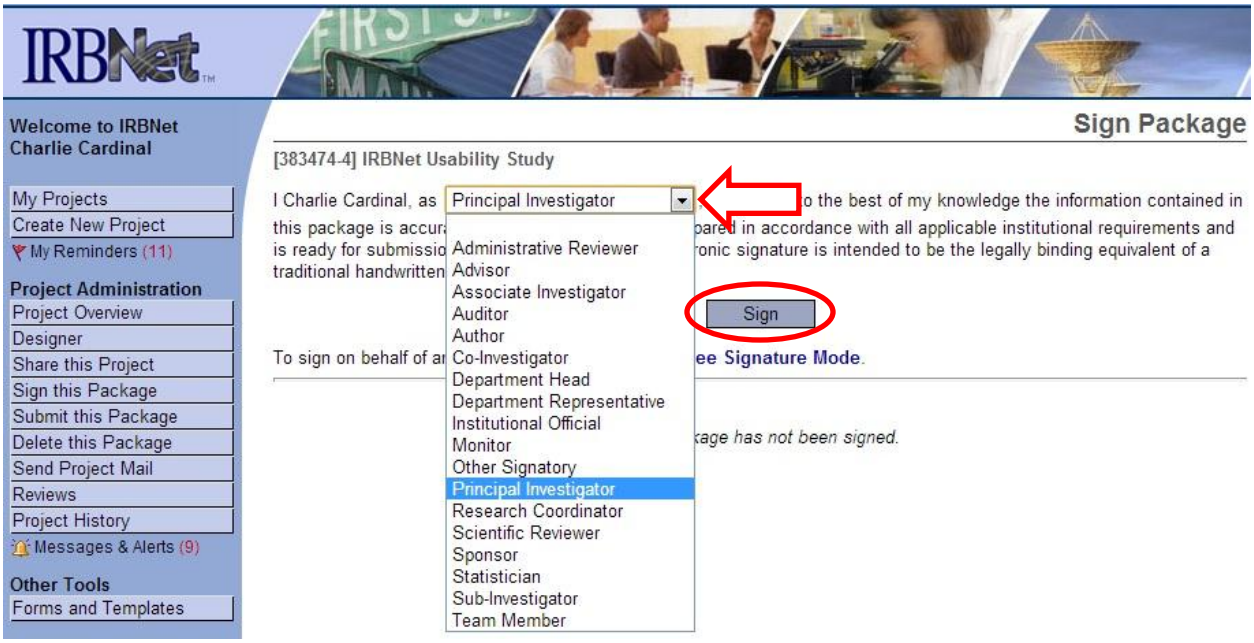
10. In the Document Type box, select the category the bests matches the document you are uploading. If you are uploading the IRB Continuing Review Form, select "Continuing Review/Progress Report". If you are uploading supporting documentation, pick the best match, if there is no match, select "Other". Click **"Choose File"** (arrow) to browse your computer for the desired file. Once found, click **"Attach"** to upload the file to your package.



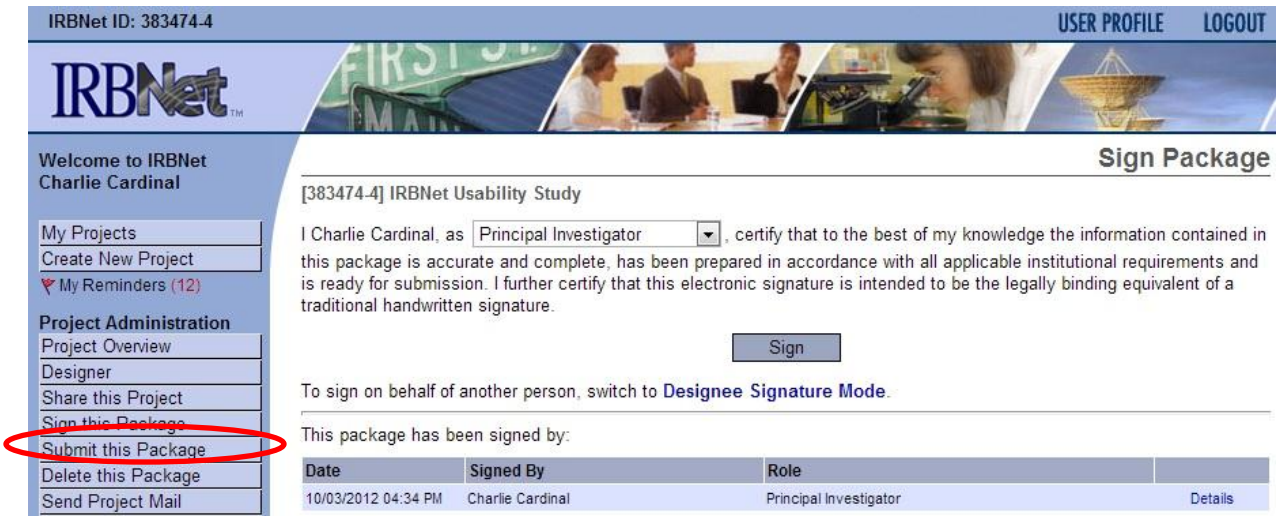
11. **Repeat steps 9 and 10 for all additional supporting documents** until they have been added to your package (if necessary).
12. Click **"Sign this Package"** under the **Project Administration** menu on the left side of the screen.


Welcome to IRBNet
Charlie Cardinal
My Projects
Create New Project
My Reminders (11)
Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Reviews
Project History
Messages & Alerts (9)
Designer
[383474-4] IRBNet Usability Study
Step 1:
Download blank forms, document templates and reference materials to assist you in assembling your document package.
Select a Library:
Ball State University IRB, Muncie, IN
Select a Document:
Child Assent (Sample)
Download
Step 2:
Assemble your document package. In addition to adding project documents to your package, IRBNet also allows you to link your project team's Training & Credentials to your package.
New and Revised Documents in this Package:
Document Type
Description
Last Modified
Continuing Review/Progress Report
Annual Continuing Review Form
10/03/2012 12:57 PM
There are no Training & Credentials records linked to this package.
Link / Un-Link Training Records

13. Once at the **Sign Package** screen, indicate your **project role** (arrow) and click **"Sign".**

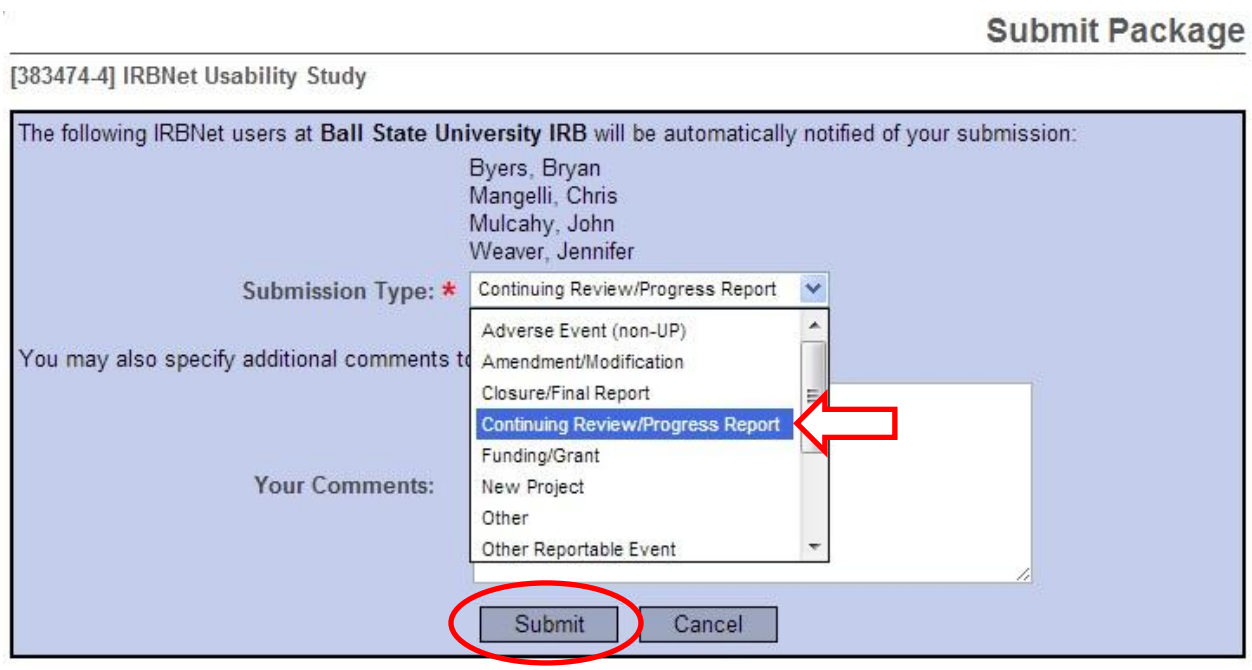


14. Your Annual Continuing Review is now ready to submit, click **"Submit this Package"** under the **Project Administration** menu.


IRBNet ID: 383474-4
USER PROFILE
LOGOUT
IRBNet
Welcome to IRBNet
Charlie Cardinal
My Projects
Create New Project
My Reminders (12)
Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Sign Package
[383474-4] IRBNet Usability Study
I Charlie Cardinal, as Principal Investigator, certify that to the best of my knowledge the information contained in this package is accurate and complete, has been prepared in accordance with all applicable institutional requirements and is ready for submission. I further certify that this electronic signature is intended to be the legally binding equivalent of a traditional handwritten signature.
Sign
To sign on behalf of another person, switch to Designee Signature Mode.
This package has been signed by:
Date
Signed By
Role
10/03/2012 04:34 PM
Charlie Cardinal
Principal Investigator
Details

15. Search for and select the proper review body at Ball State University (IRB, IACUC, IBC) and click **"Continue".**

16. Select **"Continuing Review/Progress Report"** for **Submission Type** (arrow), and then click **"Submit".**



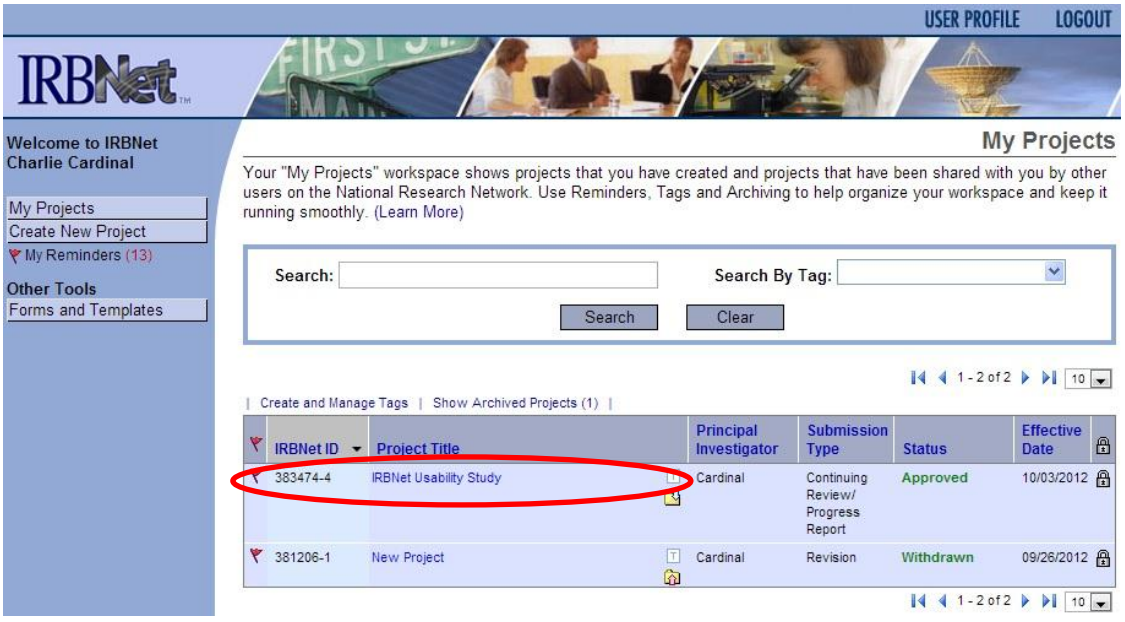
Adverse Events Submission

NOTE: Non-serious adverse events (i.e. loss of non-identifiable data) must be submitted to the Office of Research Integrity within 5 business days. **Serious adverse events (i.e. loss of identifiable data, injury, and/or death) must be reported within 24 hours.**

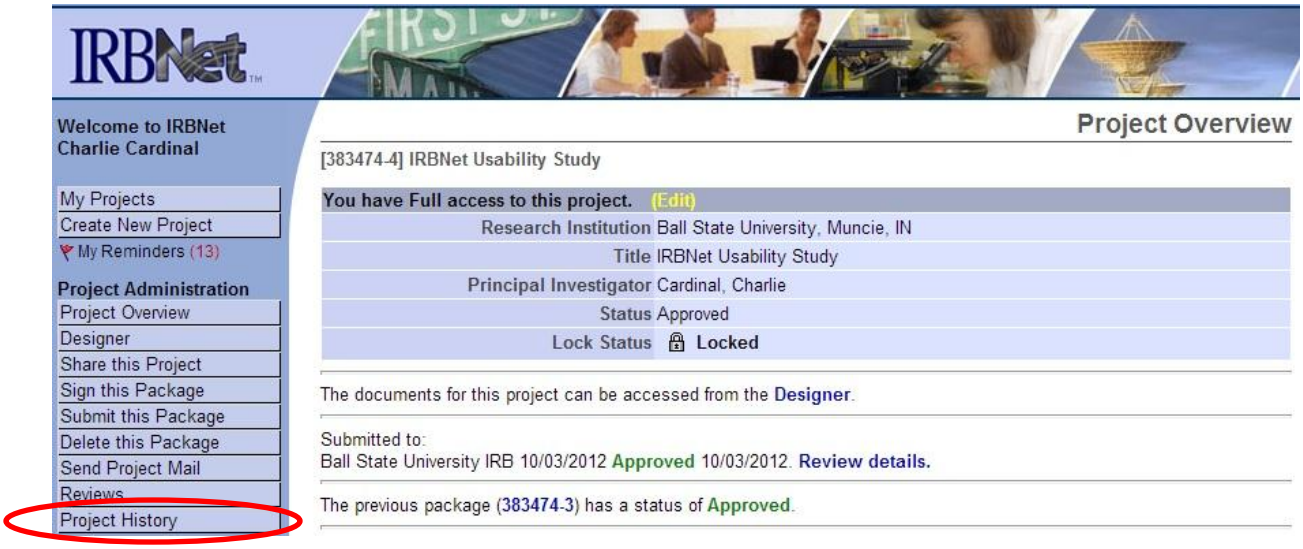
1. Login to www.irbnet.org with your username and password.
2. Select **"My Projects"** on the left side of the screen.

USER PROFILE
LOGOUT
IRBNet
Welcome to IRBNet
Charlie Cardinal
My Projects
Create New Project
My Reminders (11)
Other Tools
Forms and Templates
My Projects
Your "My Projects" workspace shows projects that you have created and projects that have been shared with you by other users on the National Research Network. Use Reminders, Tags and Archiving to help organize your workspace and keep it running smoothly. (Learn More)
Search:
Search By Tag:
Search
Clear
1 - 2 of 2
10

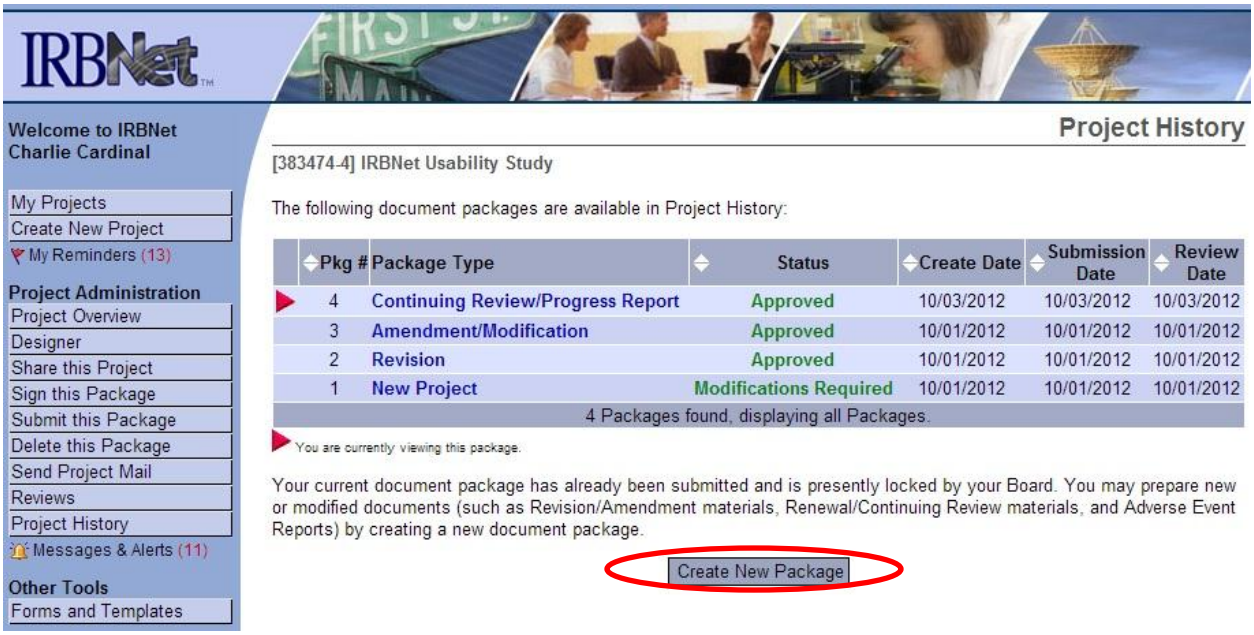
3. Select the project for which you want to submit an adverse event.



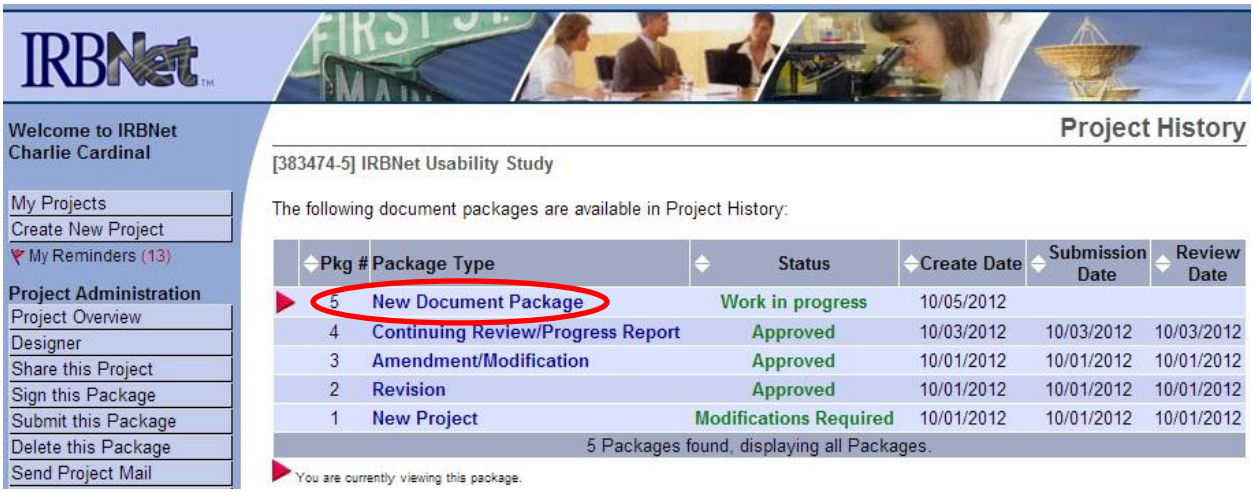
4. Select **"Project History"** under the **Project Administration** menu.



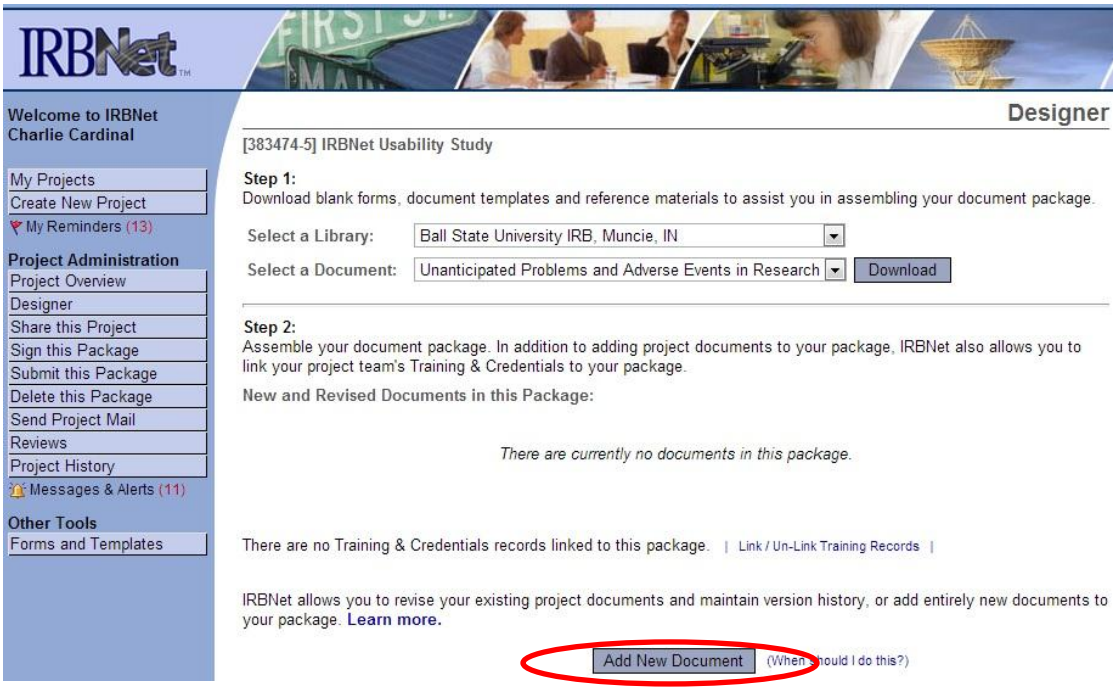
5. Click **"Create New Package"** at the bottom of the page.


IRBNet
Welcome to IRBNet
Charlie Cardinal
My Projects
Create New Project
My Reminders (13)
Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Reviews
Project History
Messages & Alerts (11)
Other Tools
Forms and Templates
Project History
[383474-4] IRBNet Usability Study
The following document packages are available in Project History:
Pkg # Package Type Status Create Date Submission Date Review Date
4 Continuing Review/Progress Report Approved 10/03/2012 10/03/2012 10/03/2012
3 Amendment/Modification Approved 10/01/2012 10/01/2012 10/01/2012
2 Revision Approved 10/01/2012 10/01/2012 10/01/2012
1 New Project Modifications Required 10/01/2012 10/01/2012 10/01/2012
4 Packages found, displaying all Packages.
You are currently viewing this package.
Your current document package has already been submitted and is presently locked by your Board. You may prepare new or modified documents (such as Revision/Amendment materials, Renewal/Continuing Review materials, and Adverse Event Reports) by creating a new document package.
Create New Package

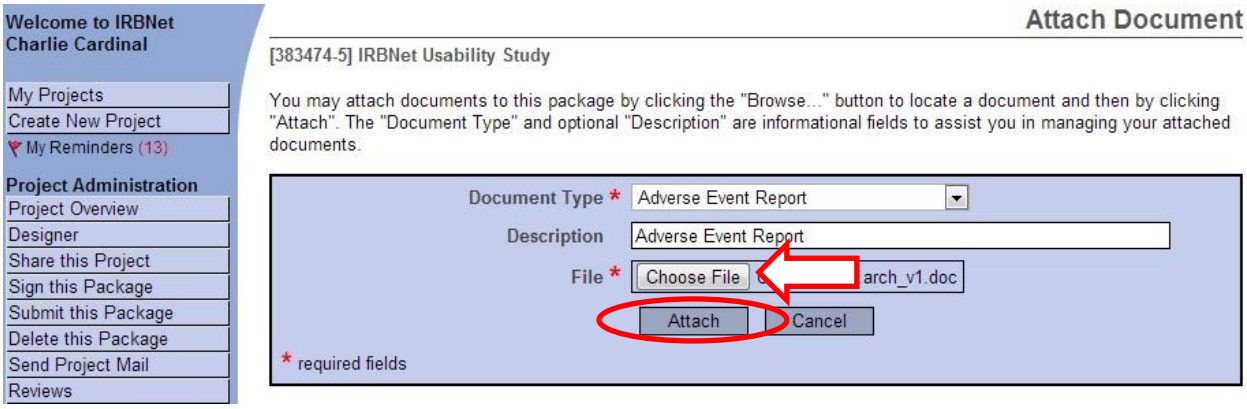
6. **"New Document Package"** will appear, click this to be taken to the **Designer** page.


IRBNet
Welcome to IRBNet
Charlie Cardinal
My Projects
Create New Project
My Reminders (13)
Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Project History
[383474-5] IRBNet Usability Study
The following document packages are available in Project History:
Pkg # Package Type Status Create Date Submission Date Review Date
5 New Document Package Work in progress 10/05/2012
4 Continuing Review/Progress Report Approved 10/03/2012 10/03/2012 10/03/2012
3 Amendment/Modification Approved 10/01/2012 10/01/2012 10/01/2012
2 Revision Approved 10/01/2012 10/01/2012 10/01/2012
1 New Project Modifications Required 10/01/2012 10/01/2012 10/01/2012
5 Packages found, displaying all Packages.
You are currently viewing this package.

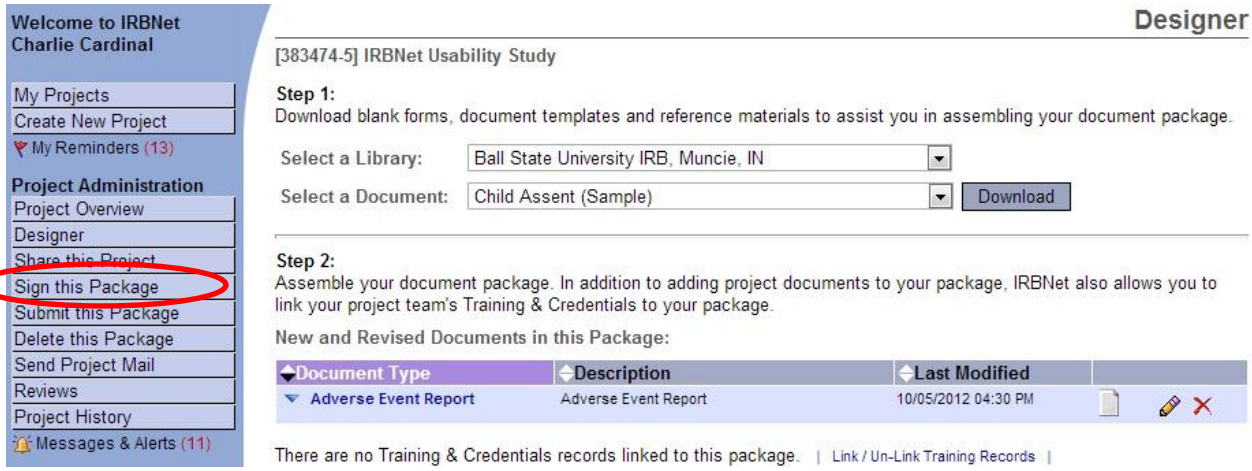
7. Fill out and complete the IRB Adverse Event form.
    a. This can be obtained in the Forms and Templates section of IRBNet.
8. Click **"Add New Document"** near the middle of the screen.


IRBNet
Welcome to IRBNet
Charlie Cardinal
My Projects
Create New Project
My Reminders (13)
Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Reviews
Project History
Messages & Alerts (11)
Other Tools
Forms and Templates
Designer
[383474-5] IRBNet Usability Study
Step 1:
Download blank forms, document templates and reference materials to assist you in assembling your document package.
Select a Library: Ball State University IRB, Muncie, IN
Select a Document: Unanticipated Problems and Adverse Events in Research
Download
Step 2:
Assemble your document package. In addition to adding project documents to your package, IRBNet also allows you to link your project team's Training & Credentials to your package.
New and Revised Documents in this Package:
There are currently no documents in this package.
There are no Training & Credentials records linked to this package. | Link / Un-Link Training Records |
IRBNet allows you to revise your existing project documents and maintain version history, or add entirely new documents to your package. Learn more.
Add New Document
(When should I do this?)

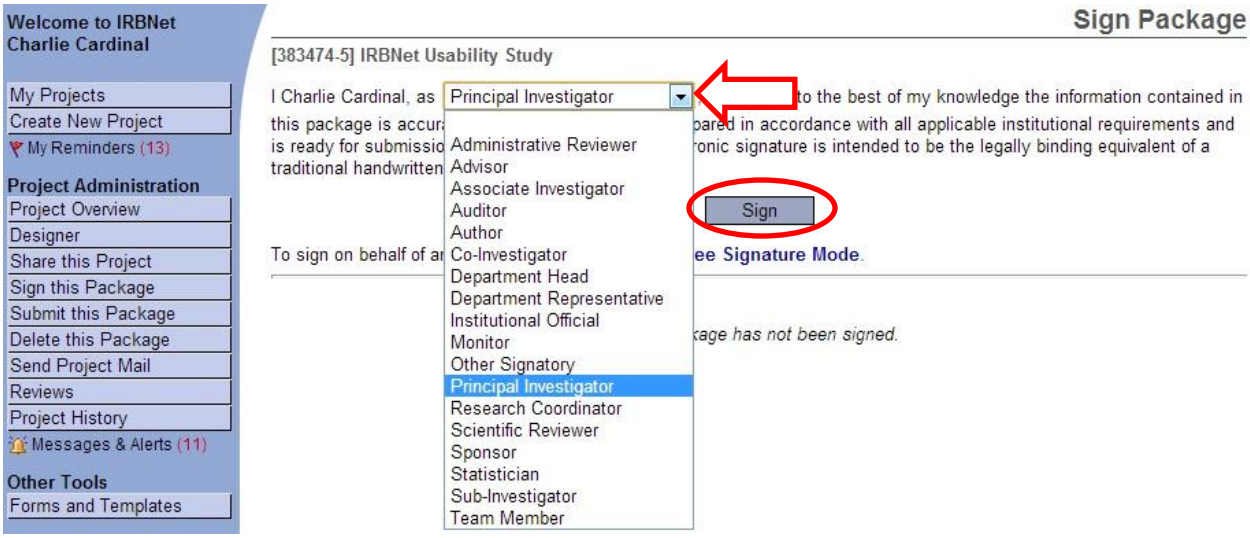
9. In the Document Type box, select the category the bests matches the document you are uploading. If this is an **adverse event or serious adverse event** select "**Adverse Event Report".** If this is an **Unanticipated Problem** select "**Unanticipated Problem Report"**. Click **"Choose File"** (arrow) to browse your computer for the desired file. Once found, click **"Attach"** to upload the file to your package.



10. Click **"Sign this Package"** under the **Project Administration** menu on the left side of the screen.


Welcome to IRBNet
Charlie Cardinal
My Projects
Create New Project
My Reminders (13)
Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Reviews
Project History
Messages & Alerts (11)
Designer
[383474-5] IRBNet Usability Study
Step 1:
Download blank forms, document templates and reference materials to assist you in assembling your document package.
Select a Library:
Ball State University IRB, Muncie, IN
Select a Document:
Child Assent (Sample)
Download
Step 2:
Assemble your document package. In addition to adding project documents to your package, IRBNet also allows you to link your project team's Training & Credentials to your package.
New and Revised Documents in this Package:
Document Type
Description
Last Modified
Adverse Event Report
Adverse Event Report
10/05/2012 04:30 PM
There are no Training & Credentials records linked to this package.
Link / Un-Link Training Records

11. Once at the **Sign Package** screen, indicate your **project role** (arrow) and click **"Sign".**



12. Your Adverse Event form is now ready to submit, click **"Submit this Package"** under the **Project Administration** menu.

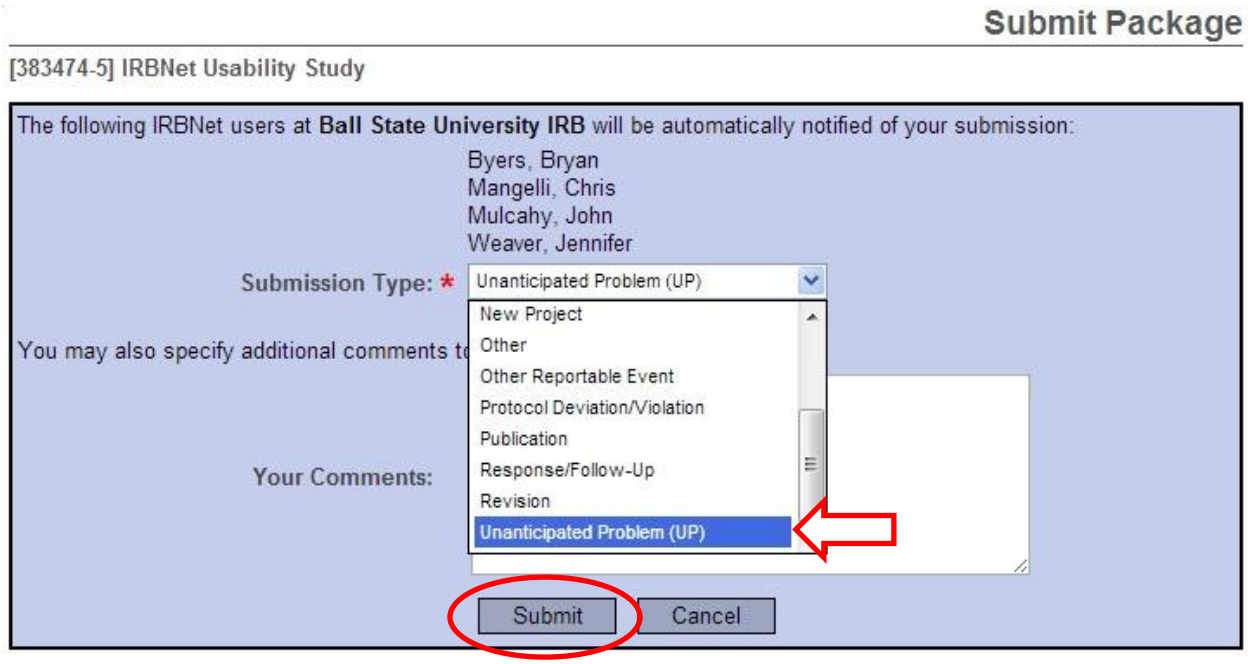
Welcome to IRBNet
Charlie Cardinal
My Projects
Create New Project
My Reminders (14)
Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Sign Package
[383474-5] IRBNet Usability Study
I Charlie Cardinal, as Principal Investigator, certify that to the best of my knowledge the information contained in this package is accurate and complete, has been prepared in accordance with all applicable institutional requirements and is ready for submission. I further certify that this electronic signature is intended to be the legally binding equivalent of a traditional handwritten signature.
Sign
To sign on behalf of another person, switch to Designee Signature Mode.
This package has been signed by:
Date
Signed By
Role
10/05/2012 04:33 PM
Charlie Cardinal
Principal Investigator
Details

13. Search for and select the proper review body at Ball State University (IRB, IACUC, IBC) and click **"Continue".**

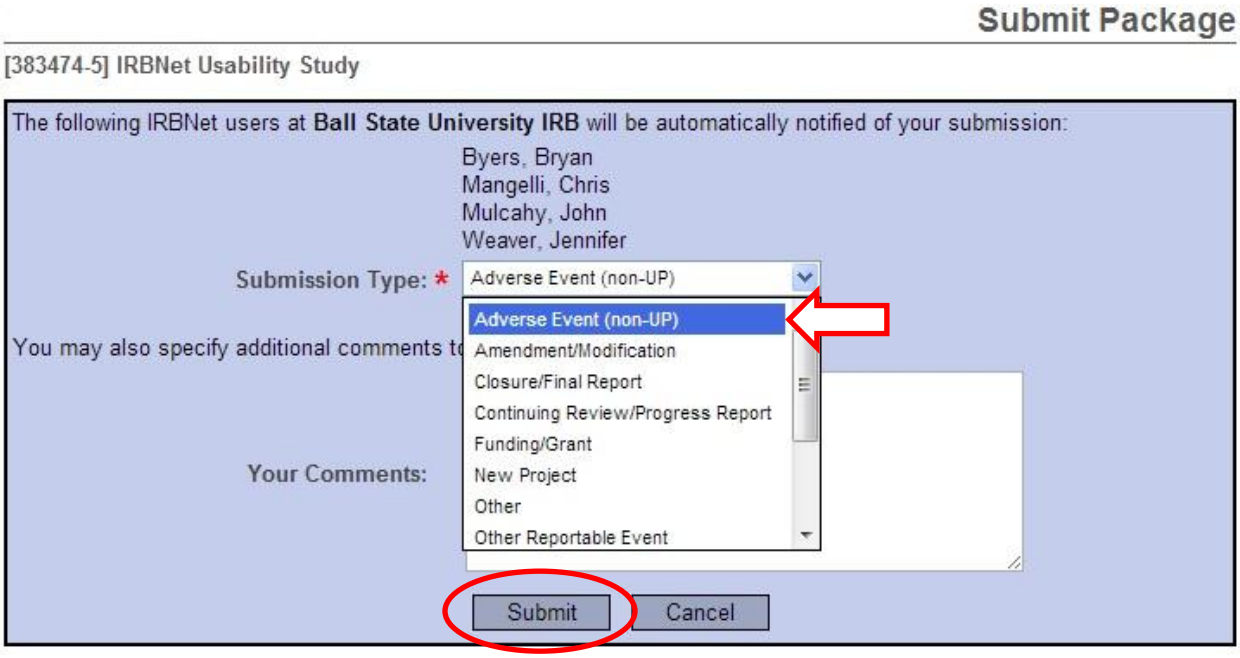
UNANTICIPATED PROBLEM SUBMISSION SEE STEP 14

SERIOUS ADVERSE EVENT AND ADVERSE EVENT SUBMISSIOM SEE STEP 15

14. Select **"Unanticipated Problem (UP)"** for **Submission Type** (arrow), and then click **"Submit".** (ORI **must** be contacted within **5 days** of the unanticipated problem.)



15. Select **"Adverse Event (non-UP)"** for **Submission Type** (arrow), and then click **"Submit".**
(ORI **must** be contacted within **24 hours** of the unanticipated problem.)



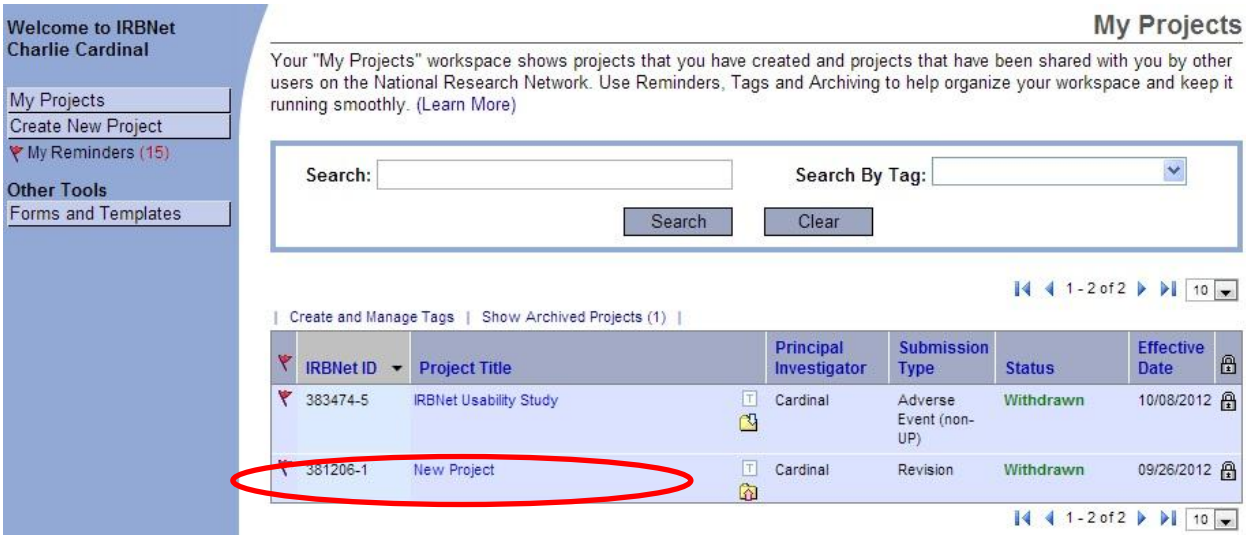
Final Report Submission (Expedited and Full Board)

When your project is complete, you will submit a final report submission to close your project on IRBNet.

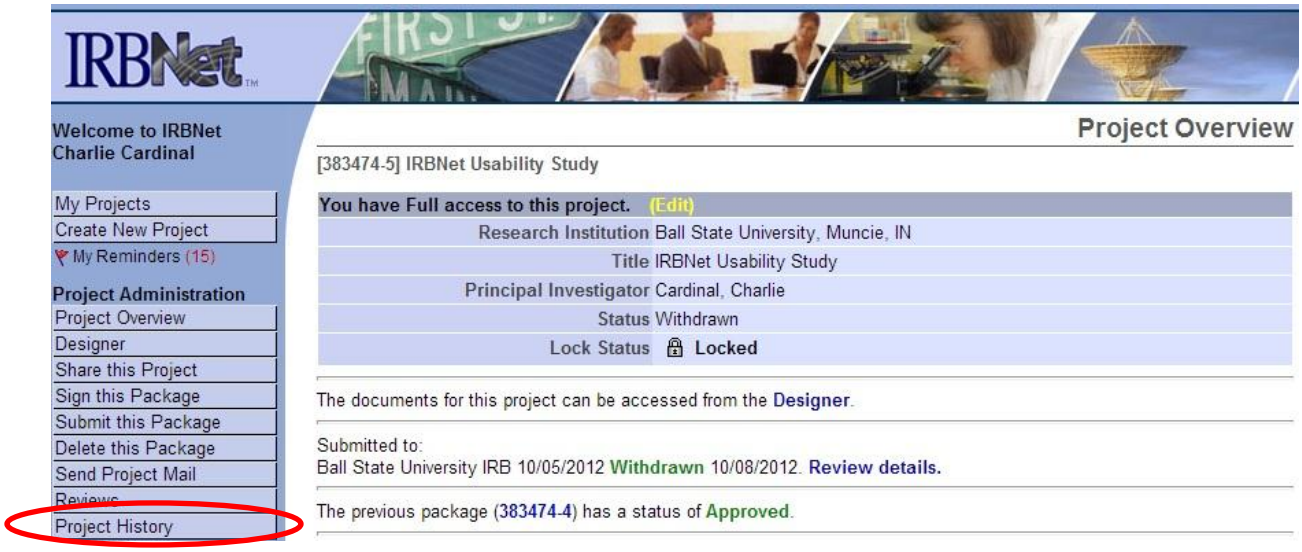
1. Login to www.irbnet.org with your username and password.
2. Select **"My Projects"** on the left side of the screen.

USER PROFILE
LOGOUT
IRBNet
Welcome to IRBNet
Charlie Cardinal
My Projects
Create New Project
My Reminders (11)
Other Tools
Forms and Templates
My Projects
Your "My Projects" workspace shows projects that you have created and projects that have been shared with you by other users on the National Research Network. Use Reminders, Tags and Archiving to help organize your workspace and keep it running smoothly. (Learn More)
Search:
Search By Tag:
Search
Clear
1 - 2 of 2
10

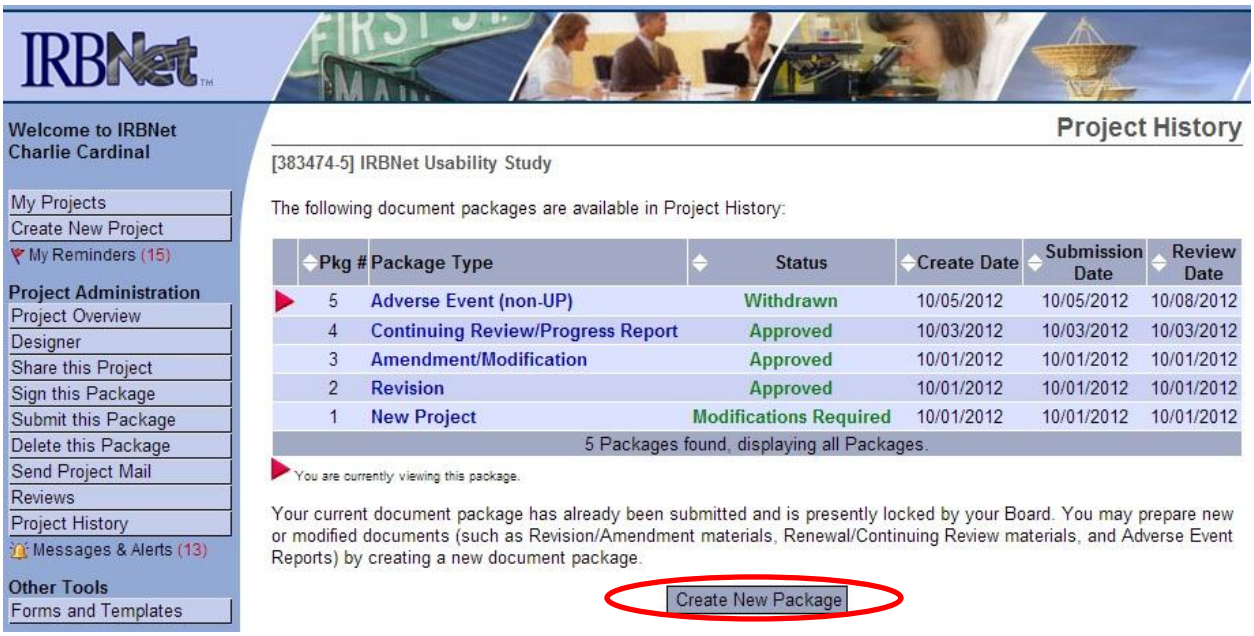
3. Select the project for which you want to submit a Final Report.



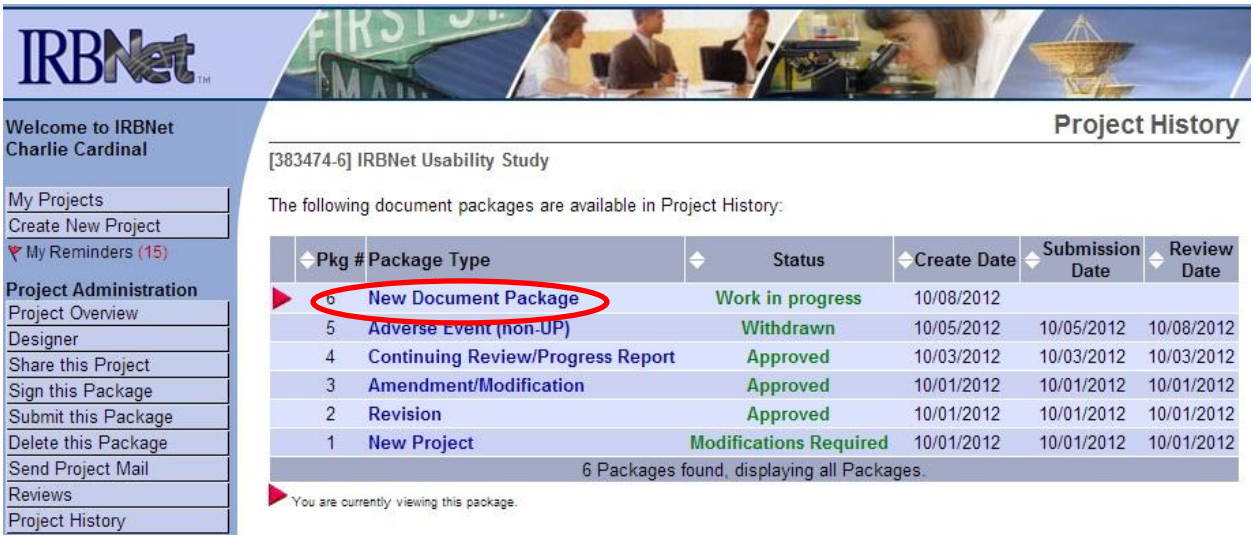
4. Select **"Project History"** under the **Project Administration** menu.



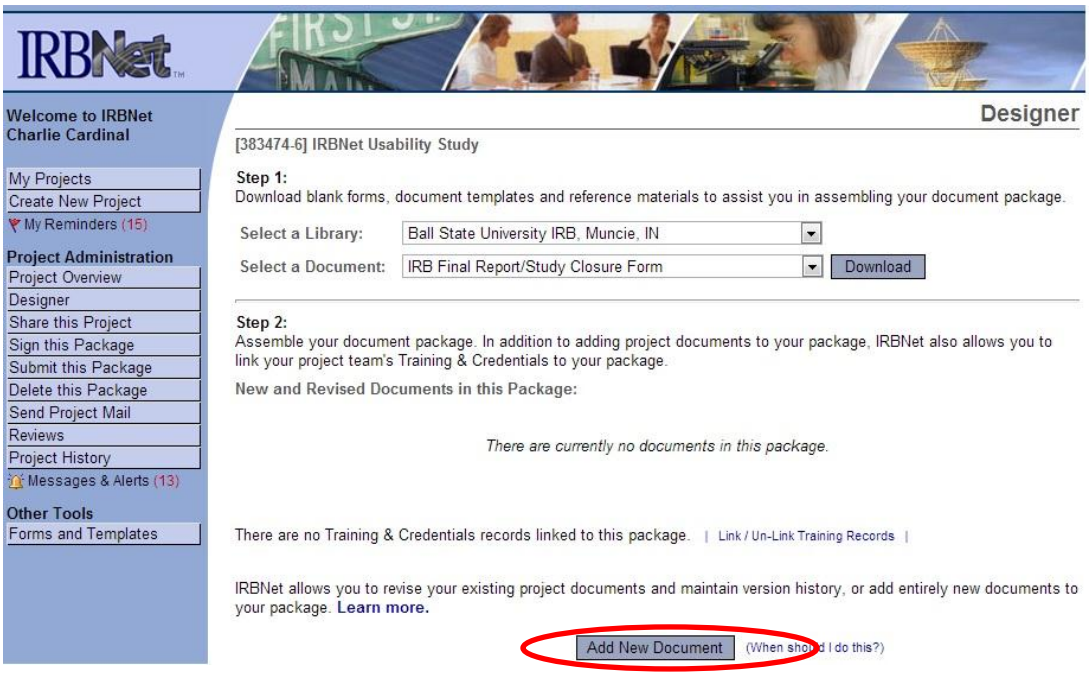
5. Click **"Create New Package"** at the bottom of the page.


IRBNet
Welcome to IRBNet
Charlie Cardinal
My Projects
Create New Project
My Reminders (15)
Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Reviews
Project History
Messages & Alerts (13)
Other Tools
Forms and Templates
Project History
[383474-5] IRBNet Usability Study
The following document packages are available in Project History:
Pkg # Package Type Status Create Date Submission Date Review Date
5 Adverse Event (non-UP) Withdrawn 10/05/2012 10/05/2012 10/08/2012
4 Continuing Review/Progress Report Approved 10/03/2012 10/03/2012 10/03/2012
3 Amendment/Modification Approved 10/01/2012 10/01/2012 10/01/2012
2 Revision Approved 10/01/2012 10/01/2012 10/01/2012
1 New Project Modifications Required 10/01/2012 10/01/2012 10/01/2012
5 Packages found, displaying all Packages.
You are currently viewing this package.
Your current document package has already been submitted and is presently locked by your Board. You may prepare new or modified documents (such as Revision/Amendment materials, Renewal/Continuing Review materials, and Adverse Event Reports) by creating a new document package.
Create New Package

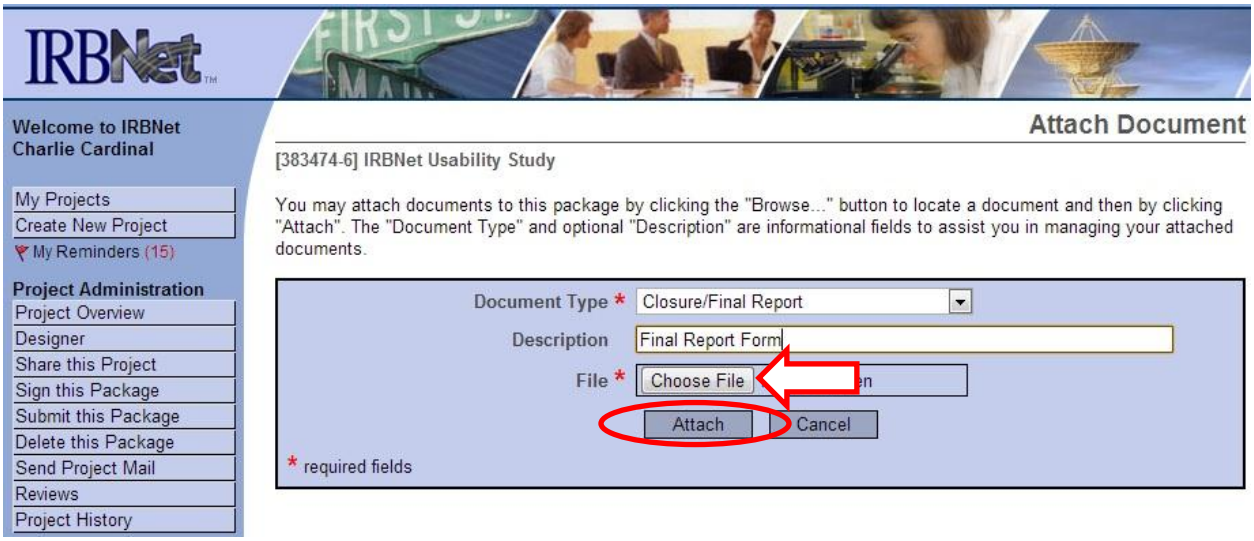
6. **"New Document Package"** will appear, click this to be taken to the **Designer** page.


IRBNet
Welcome to IRBNet
Charlie Cardinal
My Projects
Create New Project
My Reminders (15)
Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Reviews
Project History
Project History
[383474-6] IRBNet Usability Study
The following document packages are available in Project History:
Pkg # Package Type Status Create Date Submission Date Review Date
6 New Document Package Work in progress 10/08/2012
5 Adverse Event (non-UP) Withdrawn 10/05/2012 10/05/2012 10/08/2012
4 Continuing Review/Progress Report Approved 10/03/2012 10/03/2012 10/03/2012
3 Amendment/Modification Approved 10/01/2012 10/01/2012 10/01/2012
2 Revision Approved 10/01/2012 10/01/2012 10/01/2012
1 New Project Modifications Required 10/01/2012 10/01/2012 10/01/2012
6 Packages found, displaying all Packages.
You are currently viewing this package.

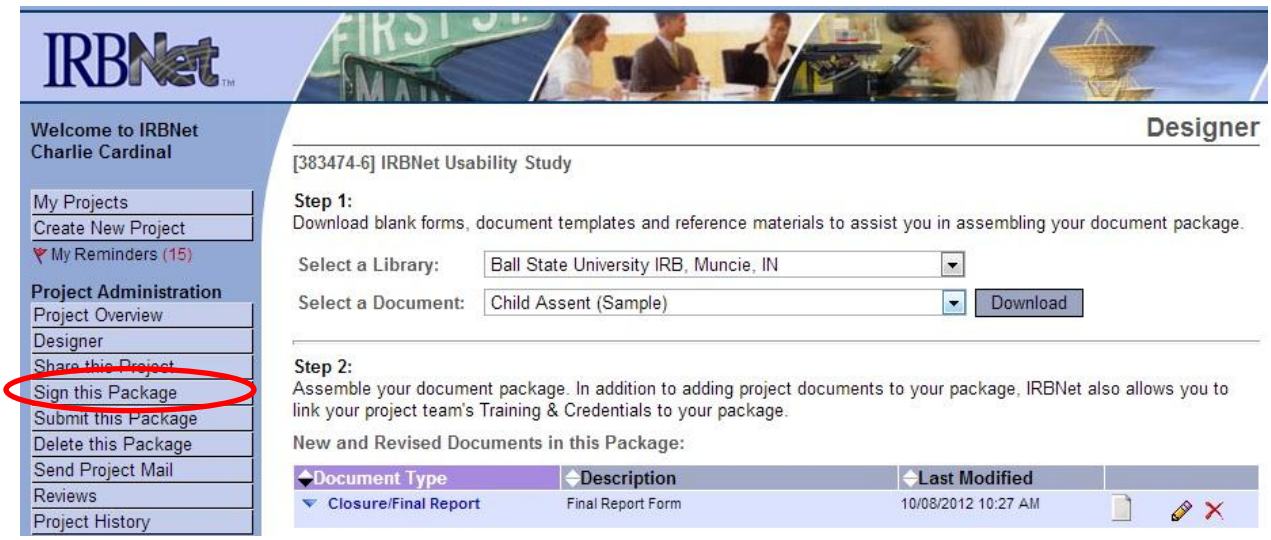
7. Fill out and complete the IRB Final Report form.
    b. This can be obtained in the Forms and Templates section of IRBNet.
8. Click **"Add New Document"** near the middle of the screen.


IRBNet
Welcome to IRBNet
Charlie Cardinal
My Projects
Create New Project
My Reminders (15)
Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Reviews
Project History
Messages & Alerts (13)
Other Tools
Forms and Templates
Designer
[383474-6] IRBNet Usability Study
Step 1:
Download blank forms, document templates and reference materials to assist you in assembling your document package.
Select a Library: Ball State University IRB, Muncie, IN
Select a Document: IRB Final Report/Study Closure Form
Download
Step 2:
Assemble your document package. In addition to adding project documents to your package, IRBNet also allows you to link your project team's Training & Credentials to your package.
New and Revised Documents in this Package:
There are currently no documents in this package.
There are no Training & Credentials records linked to this package. | Link / Un-Link Training Records |
IRBNet allows you to revise your existing project documents and maintain version history, or add entirely new documents to your package. Learn more.
Add New Document (When should I do this?)

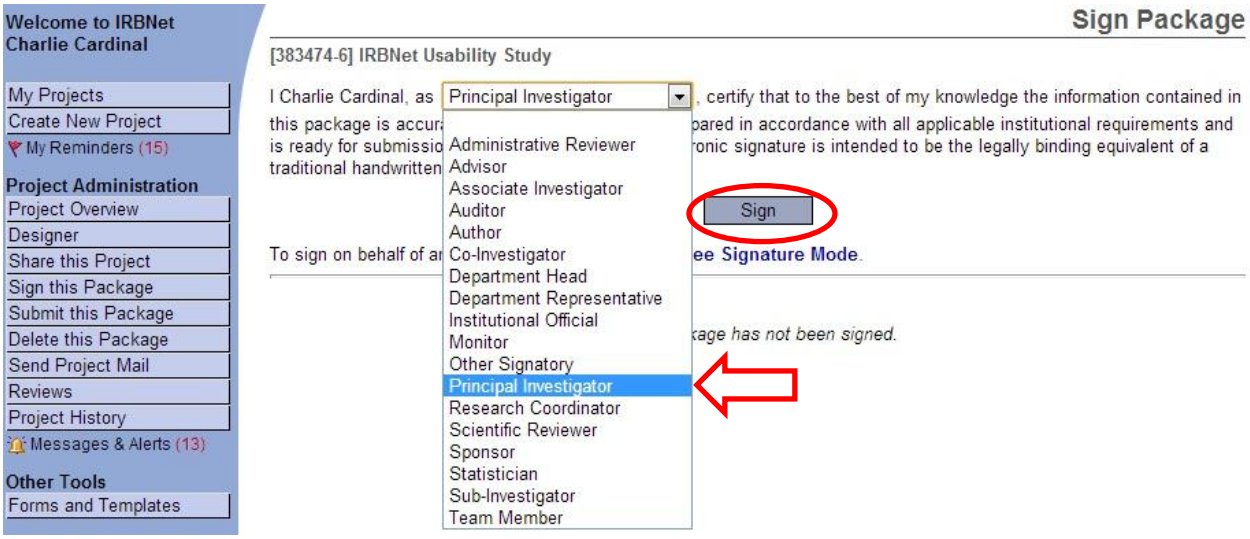
9. In the Document Type box, select the category the bests matches the document you are uploading. If you are uploading the IRB Final Report, select "Closure/Final Report". Click **"Choose File"** (arrow) to browse your computer for the desired file. Once found, click **"Attach"** to upload the file to your package.



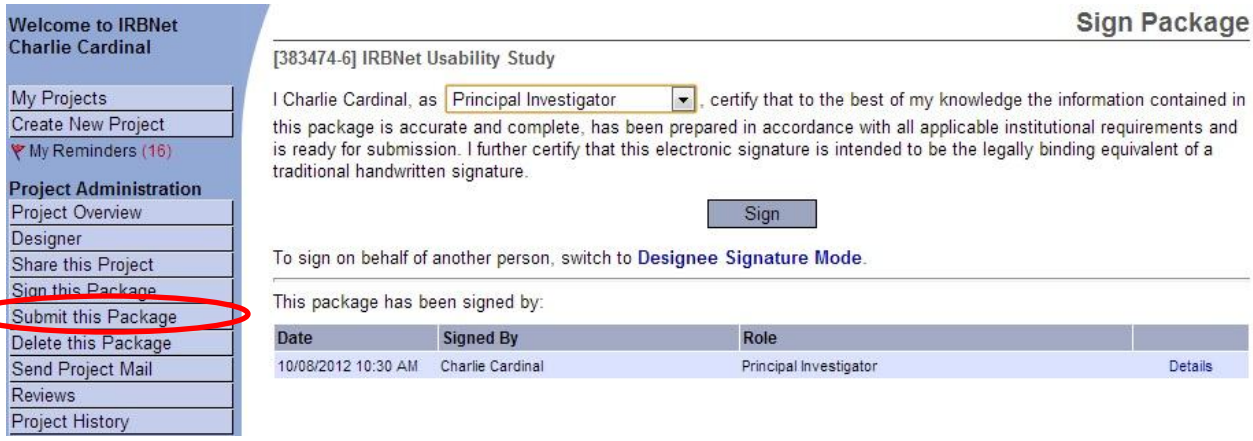
10. Click **"Sign this Package"** under the **Project Administration** menu on the left side of the screen.



11. Once at the **Sign Package** screen, indicate your **project role** (arrow) and click **"Sign".**



12. Your Final Report/ Study Closure form is now ready to submit, click **"Submit this Package"** under the **Project Administration** menu.


Welcome to IRBNet
Charlie Cardinal
My Projects
Create New Project
My Reminders (16)
Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Reviews
Project History
Sign Package
[383474-6] IRBNet Usability Study
I Charlie Cardinal, as Principal Investigator, certify that to the best of my knowledge the information contained in
this package is accurate and complete, has been prepared in accordance with all applicable institutional requirements and
is ready for submission. I further certify that this electronic signature is intended to be the legally binding equivalent of a
traditional handwritten signature.
Sign
To sign on behalf of another person, switch to Designee Signature Mode.
This package has been signed by:
Date
Signed By
Role
10/08/2012 10:30 AM
Charlie Cardinal
Principal Investigator
Details

13. Search for and select the proper review body at Ball State University (IRB, IACUC, IBC) and click **"Continue".**

14. Select **"Closure/Final Report** for **Submission Type** (arrow), and then click **"Submit".**